Jeffrey C. Block, *pro hac vice*
Jacob A. Walker (SBN 271217)
Michael D. Gaines, *pro hac vice*
BLOCK & LEVITON LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
(617) 398-5600 phone
(617) 507-6020 fax
jake@blockleviton.com
jeff@blockleviton.com
michael@blockleviton.com

Whitney Street (SBN 223870)
BLOCK & LEVITON LLP
100 Pine Street, Suite 1250
San Francisco, CA 94111
(415) 968-1852 phone
whitney@blockleviton.com

Attorneys for Lead Plaintiff Jeffrey M. Fiore and the Class

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, *Individually and on Behalf of All Others Similarly Situated,* Plaintiff, v. TRICIDA, INC. and GERRITT KLAERNER, Defendants.	Case No. 5:21-cv-00076-LHK **AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **Class Action** ***Demand for Jury Trial***

1. Plaintiff alleges the following based upon the investigation conducted by and through his attorneys, Block & Leviton LLP. This investigation included, but was not limited to, interviews of certain former employees of Tricida, and a review and analysis of (i) Tricida's public filings with the U.S. Securities and Exchange Commission ("SEC"), (ii) transcripts of Tricida's public conference calls, (iii) Tricida's press releases, (iv) independent media reports regarding Tricida, (v) securities analysts' reports and advisories about the Company, (vi) other public statements issued by the Company, and (vii) media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

2. This is a securities class action alleging violations of §§10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5, 17 C.F.R. § 240.10b-5, as promulgated thereunder, against Defendants Tricida, Inc. ("Tricida" or the "Company") and Gerrit Klaerner, Ph.D. who founded Tricida and has served as Tricida's Chief Executive Officer and President since August 2013 and is a member of its Board of Directors.

3. This action is brought on behalf of all investors who purchased Tricida common stock during the period June 28, 2018 through February 25, 2021 (the "Class Period").

4. The case concerns materially false and misleading statements and omissions of material facts about Tricida's attempts to gain approval from the United States Food and Drug Administration ("FDA") for its lead investigational drug candidate is veverimer (TRC101), "a non-absorbed, orally administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract." Veverimer is intended to slow the progression of chronic kidney disease ("CKD") through the treatment of metabolic acidosis.

5. Tricida conducted a single Phase 3 study for veverimer and sought approval under the FDA's Accelerated Drug Application ("ADA") program. To obtain approval under the ADA, a pharmaceutical company also must conduct a valid postmarketing trial.

6. In May 2018, before the Class Period begins, Tricida completed its phase 3 study for veverimer ("TRCA-301"). In a press release dated June 5, 2018, Tricida announced that

TRCA-301, "was conducted at 47 sites in the United States and Europe," and "met both its primary and secondary endpoints in a statistically significant manner."

7. Based on the strength of these trial results, Tricida went public on June 28, 2018, selling 13,455,000 million shares of its common stock to the class at $19 per share (including the exercise of options by the underwriters of the offering) and raising $255.6 million. Shares began to trade on Nasdaq on June 28, 2018. The offering registration statement, and its accompanying prospectus, misrepresented material facts, and omitted to reveal material facts necessary to make the statements that were made therein, not materially misleading. Specifically, the prospectus informed investors that Tricida "completed [its] pivotal Phase 3 clinical trial, TRCA-301. The double blind, randomized, placebo-controlled trial enrolled 217 subjects with Stage 3b or 4 CKD (an estimated glomerular filtration rate, or eGFR, of 20 to 40 mL/min/1.73m2) and low blood bicarbonate levels (between 12 mEq/L and 20 mEq/L). *We conducted the trial at 47 sites in the United States and Europe*." June 27, 2018 Prospectus, at 107.

8. The prospectus also purported to caution investors that:

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice.* Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

June 27, 2018 Prospectus, at 40-41.

9. These statements, which were repeated throughout the Class Period, were materially false and misleading, and omitted to reveal material facts necessary to make those

statements not misleading, which made Tricida's prospects for approval for veverimer, significantly more difficult and riskier than was revealed. Tricida ultimately revealed information from the FDA explaining the FDA's rationale for rejecting Tricida's NDA for veverimer. Tricida appealed the FDA's rejection of its NDA to the FDA's Office of New Drugs ("OND"). The OND ultimately rejected Tricida's appeal and explained the reasoning in an Appeal Denied Letter ("ADL") dated February 25, 2021:

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression. The OND also concluded that the confirmatory trial, VALOR CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial.
>
> The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND noted concerns around the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

10. As the ADL letter sets out, most trial sites for the TRCA-301/TRCA-301E trial were conducted in *Eastern* Europe and one site in particular was disproportionately responsible for enrollment. These are material facts which directly affect the viability and potential for FDA approval for a NDA and particularly one for CKD. Disclosing that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" without revealing that the trials were conducted primarily in *Eastern* Europe, and where once such site was disproportionately responsible for enrollment, rendered this statement materially misleading.

11. Demonstrating that a pivotal trial is adequate and well controlled under 21 C.F.R. § 314.126 requires showing that any foreign data are applicable to the U.S. population and U.S. medical practice. FDA, *Guidance for Industry and FDA Staff, FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions* 9 (March 2012),

https://www.fda.gov/media/83209/download; *see also* Nancy J. Stark, *Clinical Studies: Europe or the United States?*, Medical Device & Diagnostic Industry (May 1, 2004), https://www.mddionline.com/news/clinical-studies-europe-or-united-states ("FDA's most common objection to European data is related to how representative European subjects are of the U.S. patient population."). But "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ significantly" compared with Western Europe, which is generally considered to be the most U.S.-like foreign region besides Canada. Mehmet Sukru Sever, et. al., *A Roadmap for Optimizing Chronic Kidney Disease Patient Care and Patient-Oriented Research in the Eastern European Nephrology Community*, Clinical Kidney J. (Dec. 22, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7857792/. Thus, the fact that a majority of trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, raised the risk that trial participants would not be sufficiently representative of the U.S. patient population and U.S. medical practice for the FDA to accept the trial results. This, in turn, was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval.

12. Plus, given that Tricida intended to submit an NDA predicated upon only a single pivotal Phase 3 trial, Tricida knew that the TRCA-301/TRCA-301E trial would receive enhanced scrutiny from the FDA. Indeed, FDA guidance makes clear that "[a] conclusion based on two persuasive studies will always be more secure than a conclusion based on a single, comparably persuasive study." *See* FDA, *Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 13 (May 1998), https://www.fda.gov/media/71655/download. "For this reason, reliance on only a single study will generally be limited to situations in which a trial has demonstrated a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible." *Id.* One of the characteristics the FDA looks for in a single study capable of supporting an effectiveness claim is "a large multicenter study in which (1) no single study site

provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen." *Id.*

13. Tricida knew the patient enrollment details for its own study, TRCA-301/TRCA-301E, and it knew that data from one high-enrolling clinical site had a disproportionate impact on the trial's results. Indeed, Tricida knew enough to attempt to caution investors about its trial data from being outside the United States and that such data *"should also be applicable to the U.S. population and U.S. medical practice."* Yet, it omitted to reveal the material fact that the data on which TRCA-301 rested on was from a patient population the majority of which the FDA did not consider applicable to the U.S. population. Accordingly, "the credibility of [Tricida's] multicenter study [was] diminished," *id.*, so the study faced a significant uphill challenge to demonstrate effectiveness on its own (notwithstanding the statistically significant results observed in the trial). This information was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. The omission of this material fact rendered the statements that the Phase 3 trial was "multi-center" and "conducted at 47 sites in the United States and Europe" materially false and misleading.

14. Defendants' statements about Tricida's postmarketing trial were also misleading. Tricida represented to investors that "We had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial and initiated the trial in late 2018 in the United States and other countries with an anticipated sample size of approximately 1,600 subjects." This was false as Tricida was to conduct its postmarketing trial with approximately 4,000 patients but, early on, learned it was having tremendous difficulty recruiting patients for its study. So, Tricida proceeded with its study with only 1,600 patients. The FDA never agreed to this patient size as the ADL revealed, "the confirmatory trial, VALOR CKD, is underpowered to detect the [predicted] effect size (13%)."

15. On March 28, 2019, Chief Financial Officer Geoffrey M. Parker reported that Tricida's cash, cash equivalents, and investments totaled $243.4 million at the end of 2018, which, would only allow the Company to fund its "anticipated operating expenses and capital expenditure requirements into 2021," i.e. "the initial commercial launch period for TRC101."

The $243 million was most of the proceeds from Tricida's initial public offering. To satisfy its future cash needs, on April 8, 2019, Tricida sold an additional 6.44 million shares of common stock to the class, at $36 per share, raising $231.8 million in a secondary stock offering. In total, Tricida sold almost $500 million of common stock based on false representations about the prospects for veverimer. Additionally, Klaerner sold almost $10 million of his common stock during the Class Period while he was touting the prospects for veverimer's approval.

16. In May 2020, Tricida executives met with representatives from the FDA and learned the following:

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials *and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.*

Tricida neither revealed what it learned from the FDA in its May 2020 meeting, nor that it expected to receive a Complete Response Letter ("CRL") from the FDA regarding its NDA for vevirimer, until it filed its Second Quarter 10-Q with the Securities and Exchange Commission ("SEC") on August 6, 2020.

17. Despite learning the truth at the May 2020 meeting, Tricida and Klaerner misrepresented what the FDA told Tricida at that meeting. On May 7, 2020, Tricida held its 1Q20 earnings call with analysts and during the call, Klaerner stated,

> In our Day 74 letter, the FDA indicated that they plan to hold an advisory committee meeting or AdCom to discuss the application. *In our late-cycle meeting with the FDA held in May 2020, the FDA indicated it currently does not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19. In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues.* We presented our data and rationale as to why we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.
>
> Under the initial approval, we have to ensure that US patients who would be prescribed veverimer get clinically significant benefit that outweighs the risk of treatment. *Overall, while the FDA continues its review, we remain*

> *confident that our submission meets the standard for approval through the Accelerated Approval Program.*

(emphasis added). Instead of revealing what the FDA actually told Tricida, Klaerner blamed the cancellation of the AdCom meeting on Covid. This was false. Plus, by purporting to reveal discussions with the FDA from the May 2020 late-cycle meeting, without also revealing the negative feedback Tricida received regarding the deficiencies in the TRCA-301 trial data, Klaerner misled investors. Tricida did not reveal the entire truth as to the reasons underlying why the FDA found the data supporting TRCA-301 to be insufficient until February 25, 2021, when it revealed the ADL.

18. On July 15, 2020, at 5 pm, after the close of trading, Tricida issued a press release revealing that it had received a notification from the FDA "stating that, as part of its ongoing review of the Company's [NDA], the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time…. The notification does not specify the deficiencies identified by the FDA." While the notification itself may not have specified the "deficiencies identified by the FDA," Tricida already knew of those deficiencies from its May 2020 meeting and continued to conceal them from investors. Tricida's stock price plunged on July 16, 2020 on this news, falling 40% from its closing price of $26.20 per share on July 15, 2020 to close at $15.64 on July 16, 2020, wiping out over $530 million in market capitalization.

19. Tricida issued a press release on August 24, 2020, at 8:30 am, prior to the opening of trading, that it received a Complete Response Letter ("CRL") from the FDA for its NDA for veverimer. Tricida disclosed, among other things, that "According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit." Tricida's stock price fell by $3.13 per share, or 24% on this news, wiping out approximately $157 million in market capitalization.

20. On October 29, 2020, before markets opened, Tricida announced that during an End-of-Review Type A conference held October 20, 2020 with the FDA's Division of Cardiology and Nephrology—which had issued the CRL on August 21, 2020 denying Tricida's veverimer NDA—the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." But because Tricida could not provide this interim information from the VALOR-CKD trial "without compromising the integrity of the ongoing trial," additional trials would be required to gather this information. In other words, the FDA rejected the veverimer NDA because the single phase 3 trial's surrogate endpoint was not an adequate stand-in for clinical efficacy. The same press release disclosed that Tricida was "significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

21. In response to this news, Tricida's stock price fell 47% from its closing price of $8.27 per share on October 28, 2020 to close at $4.37 per share on October 29, 2020, wiping out nearly another $200 million in market capitalization.

22. Tricida issued a press release on December 8, 2020, sixteen minutes before markets closed for the day, announcing that the Company had failed to "come to a resolution with the Division of Cardiology and Nephrology on the resubmission of our NDA during our Type A meeting," submitted a Formal Dispute Resolution Request arguing that the TRCA-301 trial results are reasonably likely to predict clinical benefit, and revised the protocol for the VALOR-CKD trial. On this news, Tricida's stock price fell 17.73%, from a close of $8.12 per share on December 8, 2020 to close at $6.68 per share on December 9, 2020, wiping out yet another $72 million in market capitalization

23. Twenty-five minutes before markets closed on February 25, 2021, Tricida announced that it had received an ADL from the FDA. The ADL concluded (1) the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely

to provide a discernible reduction in CKD progression," (2) "the confirmatory trial, VALOR-CKD, is underpowered," (3) the trial results were "strongly influenced by a single site," and (4) "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population." This was the first time Tricida revealed to investors that the trial results were "strongly influenced by a single site" and that the "majority of sites" for the trials were in Eastern Europe. Tricida's stock price fell 30.57% in response to these revelations, from a closing price of $7.36 per share on February 25, 2021 to $5.11 per share a close on February 26, 2021, wiping out $93 million more in market capitalization.

24. Lead Plaintiff, Jeffrey M. Fiore, and all other investors purchased Tricida common stock at artificially inflated prices and were damaged as the truth was revealed and the artificial inflation was eliminated.

BACKGROUND

25. Tricida, founded in 2013, is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of non-absorbed therapies. Its lead investigational drug candidate is veverimer (TRC101), "a non-absorbed, orally administered polymer designed to treat metabolic acidosis by binding and removing acid from the gastrointestinal tract." Veverimer is intended to slow the progression of chronic kidney disease ("CKD") through the treatment of metabolic acidosis. Tricida planned to submit its NDA for veverimer to the FDA for review through the Agency's ADA. Under the ADA, if the Phase 3 program demonstrates clinical efficacy by achieving a predetermined surrogate endpoint, actual clinical efficacy must thereafter be demonstrated through a confirmatory postmarketing trial. Tricida used blood bicarbonate level as a surrogate endpoint.

26. In May 2018, Tricida completed the single veverimer Phase 3 trial (TRCA-301), a "multicenter, randomized, double-blind, placebo controlled" clinical trial. The Company announced on June 5, 2018 that TRCA-301, which "was conducted at 47 sites in the United States and Europe," "met both its primary and secondary endpoints in a statistically significant

manner" and that 196 of the 217 CKD patients from the Phase 3 TRCA-301 trial agreed to continue their participation in a 40-week blinded extension trial (TRCA-301E).

27. Tricida knew that the majority of trial sites were in Eastern Europe and that the trial was over-reliant on a single site for recruitment.

28. Capitalizing on the positive Phase 3 trial results, Tricida made an initial public offering ("IPO") of stock on June 28, 2018 and sold approximately $255 million in common stock to the class. The related Prospectus again touted the success of the TRCA-301 trial and said that "[b]ased on feedback from the FDA, we believe that the data from the TRCA-101, TRCA-301, and TRCA-301E trials will provide sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA for TRC101 pursuant to the [ADA]." Furthermore, the Prospectus revealed that Tricida "anticipate[d] a sample size of 1,400 to 1,600 subjects" for the confirmatory postmarketing trial (VALOR-CKD), which would be justified by use of "a quantitative predictive model developed by Navdeep Tangri, M.D., Pd.D., of the University of Manitoba, in which he modeled the relationship between the change in blood bicarbonate and the risk of kidney disease progression." Therefore, cautioned the Prospectus, Tricida "must obtain the FDA's agreement and finalize the design of our confirmatory postmarketing trial, VALOR-CKD, and completely enroll our confirmatory postmarketing trial, VALOR-CKD, prior to the submission of an NDA."

29. Tricida began enrolling and conducting the VALOR-CKD trial in the fourth quarter of 2018. But enrollment proved to be a slower process than Tricida wanted. Confidential Witness 1 ("CW1") was employed by Tricida as a Clinical Trial Assistant from October 2018 through June 2019. As a Clinical Trial Assistant, CW1's responsibilities included working with a contracted clinical research organization, PRA Health Sciences ("PRA"), to open and approve global trial sites where contracted doctors prescribed veverimer to patients as part of Tricida's clinical trials. Initially, CW1 reported to Christine Li, who was a Senior Manager. Li left the Company a few months after CW1 was hired, after which CW1 reported directly to Yuri Stasiv, who was Vice President of Clinical Operations at the time.[1] According to CW1, Tricida had set a

[1] Stasiv is now Senior Vice President of Clinical Operations at Tricida.

target of enrolling 4,000 subjects for its VALOR-CKD trial. PRA was responsible for identifying patients and sites for the clinical trial, but PRA struggled to recruit patients for the VALOR-CKD confirmatory trial. CW1 participated in numerous discussions between Tricida and PRA about whether it was "worth it" to pay to open a potential new site when the site would add few additional veverimer trial subjects. Klaerner was infuriated by the situation, and, at meetings attended by CW1 just before he left in June 2019, "screamed" at PRA employees for failing to recruit enough patients. When CW1 left Tricida in June 2019, the Company had not even recruited half of the 4,000 subjects and related target sites needed to fully enroll the VALOR-CKD trial.

30. Instead of delaying the NDA application until an adequate number of subjects could be enrolled in the confirmatory postmarketing trial, Tricida forged ahead with an underpowered confirmatory postmarketing trial. Publicly, Tricida and Klaerner continued to represent that the VALOR-CKD trial would have only 1,600 subjects by design, and they never amended their public commitment to reach agreement with the FDA on the trial design and nearly fully enroll the trial before submitting an NDA.

31. During an earnings call on March 28, 2019, Klaerner reported that Tricida had the results of the TRCA-301E extension trial, and that the combined results of the TRCA-301/TRCA-301E trial "far exceeded our expectations": Not only did the extension trial "me[e]t its primary and all secondary endpoints," but "we have observed evidence of clinical benefit in TRC101-treated subjects, including reduced all-cause mortality, slowing of CKD progression and improved physical function." Klaerner shared that "we feel good about what we've learned in the 301E study regarding safety and efficacy, increasing our confidence for a successful VALOR-CKD trial.

32. Tricida and Klaerner repeated the same statements about the success of the Phase 3 pivotal trial, its extension, and the design of the confirmatory postmarketing trial (without mentioning any of their known critical shortcomings) in each and every Tricida SEC filing and quarterly earnings call through May 2020.

33. During the Q4 2018 earnings call on March 28, 2019, Chief Financial Officer Geoffrey M. Parker reported that Tricida's cash, cash equivalents, and investments totaled $243.4 at the end of 2018, which, in conjunction with a recently amended debt facility, would only allow the Company to fund its "anticipated operating expenses and capital expenditure requirements into 2021," i.e. "the initial commercial launch period for TRC101." The Company had raised approximately $255 million in its initial public offering in June 2018, so without the funds raised in the offering, at that point in time, Tricida, would have been out of cash. Tricida needed additional money to fund anything other than a flawless accelerated approval of veverimer, and even then, there was not enough cash to fully commercialize the drug. Based on the publicly-presented prospects for FDA approval for veverimer, Tricida sold 6.44 million shares of common stock, at $36 per share, for over $231 million in a secondary stock offering completed on April 8, 2019.

34. On June 12, 2019, while speaking at the Goldman Sachs Global Healthcare Conference, Klaerner reiterated that the VALOR-CKD trial would have an enrollment of 1,600 patients. He asserted that "the study is powered to show a 30% reduction in renal progression" and reassured analysts that "we are on track to really have this sufficiently recruited to submit our NDA in the second half of this year." Curiously, he suggested that obtaining FDA approval for a new drug through the ADA was easier than through traditional FDA review:

> And when you fast-forward in all the work that we've done, from a discovery to an early development, to a late stage development, agreeing with FDA, an accelerated approval path, you -- all you expect to do is to show a surrogate effect, and then you have a post-marketing commitment that ultimately then, you confirm that, that surrogate is going to translate. Now we found ourselves with 1-year safety extension data that showed clinical benefit.

He also falsely boasted that Tricida "ha[d] the ability to submit our NDA with just one pivotal trial that shows a surrogate effect," passing off the NDA's fatal weakness as an accomplishment.

35. On September 4, 2019, Tricida announced that it had submitted the veverimer NDA through the ADA in late August 2019. And on November 14, 2019, Tricida announced that the FDA had accepted its NDA for review under the ADA and assigned a Prescription Drug User

Fee Act ("PDUFA") date of August 22, 2020. Tricida also mentioned that enrollment in the VALOR-CKD trial was estimated to be completed in mid-2020.

36. On July 15, 2020, Tricida announced in a press release that it had received a notification from the FDA "stating that, as part of its ongoing review of the Company's [NDA], the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time…. The notification does not specify the deficiencies identified by the FDA." In response to this news, on unusually heavy trading activity, Tricida's stock price dropped sharply in one day, falling $10.56 per share in response to the news to close at $15.64 per share on July 16, 2020.

37. Although the notification may not have specified the deficiencies, Tricida and Klaerner knew which deficiencies the FDA had likely referenced. Indeed, they—better than anyone—knew the shortcomings of the veverimer trials. The second quarter 2020 Form 10-Q, filed August 6, 2020 finally disclosed some deficiencies:

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.

In the same 10-Q, the Company finally conceded that "we are likely to receive … a Complete Response Letter, or CRL."

38. During an August 5, 2020 earnings call, an analyst asked Klaerner to "remind us of the process that you went through to get the FDA to sign off on the design of the pivotal study and in particular, the serum bicarbonate primary endpoint. Was there any disagreement between you and the FDA in the design? Or are you both on the same page?" Klaerner offered a carefully worded response, stating the Company had reached agreement with the FDA (1) "that we are treating a serious disease, that there is an unmet medical need and that we have a surrogate that's likely going to translate to clinical benefit," and (2) on "a quantitative understanding … of how the surrogate really impacts … the progression of kidney disease." Based on those agreements, said Klaerner, Tricida designed the TRCA-301/TRCA-301E and VALOR-CKD trials.

39. On August 24, 2020, Tricida announced that it had received the anticipated CRL and revealed that the FDA's concerns were, in fact, the very issues the FDA had raised in advance of the late cycle meeting in May 2020 (and which Tricida had always known, but never disclosed to the market). Klaerner was quoted as saying "we are pleased that the FDA has provided helpful, specific comments and indicated their willingness to continue to work with us to pursue approval of veverimer." The Company also said it would request a Type A meeting with the FDA to discuss next steps.

40. On October 29, 2020, Tricida provided an update on the Type A meeting. Tricida proposed conducting an interim analysis of data from about 500 patients in the VALOR-CKD trial, hoping that it would allow the Company to resubmit its NDA "within a matter of months," but the FDA rejected the proposal. "Based on feedback during the Type A meeting," Tricida revealed that it "now believes the FDA will also require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program and that the FDA is unlikely to rely solely on serum bicarbonate data for determination of efficacy."

41. During an analyst call the same day, Klaerner acknowledged for the first that the TRCA-301/TRCA-301E trials failed to enroll enough subjects who were representative of the U.S. patient population. Describing future enrollment in the VALOR-CKD trial, Klaerner said, "We are focusing on U.S. and Western Europe and Canada to get more patients from those regions, even though we think that patients are pretty much the same all over the world, but it does make sense to add in a few more from those more U.S.-like countries. And FDA asked us to do that."

42. The stock price took another hit on this news, falling from a closing price of $8.27 per share on October 28, 2020 to close at $4.37 per share on October 29, 2020.

43. On December 8, 2020, Tricida announced that it had revised the protocol for its VALOR-CKD trial, switching from "an adaptive design" with "an unblinded interim analysis for sample size re-estimation" to "a group sequential design, no interim analysis for sample size adjustment, and unblinded interim analyses for early stopping for efficacy after 150 primary

endpoint events … and 250 primary endpoint events … have accrued." Despite having repeatedly stated its commitment to fully enrolling or nearly fully enrolling the VALOR-CKD trial prior to NDA submission, Tricida revised the expected date by which enrollment would be completed to the end of 2022.

44. Tricida had submitted a Formal Dispute Resolution Request in December 2020 in a final attempt to convince the FDA that the magnitude and durability of serum bicarbonate change seen in the TRCA-301/TRCA-301E trial was reasonably likely to predict clinical benefit in the treatment of CKD. On February 25, 2021, Tricida revealed that it had received an Appeal Denied Letter ("ADL") from the FDA's Office of New Drugs ("OND") and shared the basis for the OND's rejection of the veverimer NDA:

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression. The OND also concluded that the confirmatory trial, VALOR CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial.
>
> The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND noted concerns around the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

45. Tricida's stock price took another hit as investors responded to this news, falling from a close of $7.36 per share on February 25, 2021, to close at $5.11 per share on February 26, 2021.

JURISDICTION AND VENUE

46. This Complaint asserts claims under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5").

47. This Court has jurisdiction over the subject matter of this action under Section 27 of the Exchange act, 15 U.S.C. § 78aa and 28 U.S.C. §§ 1331 and 1337.

48. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), (c), and (d). Many of the acts and omissions that constitute the alleged violations of law, including the dissemination to the public of untrue statements of material facts, occurred in this District.

49. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of national securities exchanges.

PARTIES

50. Lead Plaintiff Jeffrey M. Fiore, a resident of Texas, purchased Tricida common stock during the Class Period on the Nasdaq Global Select Market and was damaged thereby. *See* ECF No. 12-2, Ex. B.

51. Defendant Tricida is a Delaware corporation with principal executive offices located at 7000 Shoreline Court, Suite 201, South San Francisco, California 94080. Tricida common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "TCDA." Since its founding in 2013, the Company has incurred significant operation losses and had yet to develop any drug that the FDA approved for marketing and sales in the United States. Tricida is a control person of Gerrit Klaerner within the meaning of § 20(a) of the Exchange Act.

52. Defendant Gerrit Klaerner, Ph.D. founded Tricida and has served as Tricida's Chief Executive Officer and President since August 2013. He has also held a seat on Tricida's board of directors since July 2013. Previously, Klaerner founded Relypsa, Inc., serving as President and Director from October 2007 until June 2013. Before that, Klaener co-founded Ilypsa, Inc., serving as its Director of Technology Assessment and Business Development from January 2003 until December 2006, and as its Chief Business Officer and Senior Vice President from December 2006 until July 2007. Before Ilypsa, Klaerner was employed at Symyx

Technologies, Inc. as a Staff Scientist, Senior Staff Scientist, and Director Business Development.

53. Prior to and during the Class Period, Klaerner was responsible for complying with the Company's Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics deemed Klaerner, as Chief Executive Officer, one of the three "sole authorized spokepersons for the Company." Klaerner made or had authority over the content and dissemination of the false and misleading statements and omissions set forth herein and is liable for those false statements and omissions. Klaerner is also a control person of Tricida within the meaning of § 20(a) of the Exchange Act.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

Materially False and Misleading Statements and Omissions Before the Class Period Begins

54. On June 5, 2018, Tricida issued a press release titled "Tricida Announces Positive Pivotal Phase 3 Clinical Trial Results for TRC101 in CKD Patients with Metabolic Acidosis." The press release stated, in pertinent part,

> Tricida, Inc., a late-stage pharmaceutical company, announced results from *its pivotal Phase 3 double-blind, randomized, placebo-controlled, multi-center Phase 3 clinical trial, TRCA-301*, in 217 chronic kidney disease (CKD) patients with metabolic acidosis. TRC101 represents a first-in-class candidate for the treatment of metabolic acidosis, a common complication of CKD that can accelerate progression of kidney disease, increase the risk of muscle wasting and cause the loss of bone density.
>
> Based on the initial topline analyses, the TRCA-301 trial met both its primary and secondary endpoints in a highly statistically significant manner ($p < 0.0001$ for all primary and secondary endpoints). TRC101 was well tolerated in the TRCA-301 trial. Both active (124 subjects) and placebo groups (93 subjects) had low discontinuation rates and low rates of treatment-related adverse events.
>
> * * *
>
> *The TRCA-301 double-blind, randomized, placebo-controlled Phase 3 trial was conducted at 47 sites in the United States and Europe* and enrolled 217 Stage 3b or 4 CKD patients with baseline blood bicarbonate levels between 12 mEq/L and 20 mEq/L. Subjects were randomized in a 4:3 ratio to receive TRC101 or placebo. The study drug dosing (TRC101 or placebo) continued

> for 12 weeks once daily. The primary outcome measure was change from baseline in blood bicarbonate (Time Frame: Week 12) and included comparison of TRC101 and placebo with regard to the proportions of subjects with change from baseline in blood bicarbonate ≥ 4 mEq/L or with blood bicarbonate in the normal range (22 to 29 mEq/L). Eligible subjects that completed the TRCA-301 trial were invited to participate in a 40-week safety extension trial, TRCA-301E. Of the 208 subjects who completed the TRCA-301 trial, 196 were enrolled in the TRCA-301E safety extension trial.
>
> * * *
>
> Tricida, Inc., is a late-stage pharmaceutical company focused on the development and commercialization of TRC101, a non-absorbed, orally-dosed polymer drug designed to treat metabolic acidosis in patients with chronic kidney disease. The results of the pivotal Phase 3 clinical trial reported today, along with results from a successful double-blind, randomized, placebo-controlled Phase 1/2 trial and an ongoing safety extension trial, TRCA-301E, are intended to serve as the basis for the submission of a U.S. New Drug Application (NDA) for TRC101 under the Accelerated Approval Program of the U.S. Food and Drug Administration (FDA).

55. The statements identified in italics above were false and misleading. The statement that TRCA-301 was a "multi-center" trial "conducted at 47 sites in the United States and Europe" was materially false and misleading when made for two reasons, and Defendants knew or recklessly disregarded the truth in making the statement. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, one site in particular was disproportionately responsible for enrollment—both material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was material and stating that the TRCA-301 trial was "multi-center" and conducted "at 47 sites in the United States and Europe" was materially misleading.

56. Demonstrating that a pivotal trial is adequate and well controlled under 21 C.F.R. § 314.126 requires showing that any foreign data are applicable to the U.S. population and U.S. medical practice. FDA, *Acceptance of Foreign Clinical Studies*, *supra*, at 9; *see also* Stark, *Clinical Studies: Europe or the United States?*, *supra*. ("FDA's most common objection to European data is related to how representative European subjects are of the U.S. patient

population."). But "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ significantly" compared with Western Europe, which is generally considered to be the most U.S.-like foreign region besides Canada. Sever, *A Roadmap for Optimizing Chronic Kidney Disease Patient Care*, *supra*. Thus, the fact that a majority of trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, raised the risk that trial participants would not be sufficiently representative of the U.S. patient population and U.S. medical practice for the FDA to accept the trial results. This, in turn, was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. Accordingly, the omission of the fact that a majority of trial sites for the Phase 3 trial were in Eastern Europe from the statement that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" rendered it false and misleading.

57. Given that Tricida intended to submit an NDA predicated upon only a single pivotal Phase 3 trial, Tricida and Klaerner knew that the TRCA-301/TRCA-301E trial would receive enhanced scrutiny from the FDA. Indeed, FDA guidance makes clear that "[a] conclusion based on two persuasive studies will always be more secure than a conclusion based on a single, comparably persuasive study." FDA, *Providing Clinical Evidence of Effectiveness*, *supra*, at 13. "For this reason, reliance on only a single study will generally be limited to situations in which a trial has demonstrated a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible." *Id.* One of the characteristics the FDA looks for in a single study capable of supporting an effectiveness claim is "a large multicenter study in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen." *Id.* Tricida and Klaerner knew the patient enrollment details for its own study, and they knew that data from one high-enrolling clinical site had a disproportionate impact on the trial's results. Accordingly, Tricida and Klaerner knew that "the credibility of [its] multicenter study [was] diminished," *id.*, and therefore faced a significant uphill challenge to

demonstrate effectiveness on its own (notwithstanding the statistically significant results observed in the trial). This information was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. The omission of this information from the statement that the Phase 3 trial was "multi-center" and "conducted at 47 sites" rendered it materially false and misleading.

Materially False and Misleading Statements and Omissions Concerning the IPO

58. On June 27, 2018, Tricida filed a Form S-1/A and related Rule 424(b)(4) Prospectus in connection with the Company's IPO, both of which were signed by Defendant Klaerner. Under "Our Development Program for TRC101," the Prospectus stated,

> In May 2018, we completed our pivotal Phase 3 clinical trial, TRCA-301. The double blind, randomized, placebo-controlled trial enrolled 217 subjects with Stage 3b or 4 CKD (an estimated glomerular filtration rate, or eGFR, of 20 to 40 mL/min/1.73m2) and low blood bicarbonate levels (between 12 mEq/L and 20 mEq/L).
>
> * * *
>
> *We conducted the trial at 47 sites in the United States and Europe.*

Under "Risk Disclosures," the Prospectus stated, "*We recently completed a* randomized, double-blind, placebo-controlled, *multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301*."

59. The statements identified in italics above were false and misleading. These statements were materially false and misleading when made for two reasons, and Defendants knew, or recklessly disregard the truth in making these statements. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, one site in particular was disproportionately responsible for enrollment—both material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was material, and stating that the TRCA-301 trial was "multicenter" and conducted "at 47 sites in the United States and Europe" was materially misleading for the reasons stated in ¶¶56-57.

60. Established knowledge about foreign patient populations and FDA guidance aside, Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The Prospectus cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the Prospectus warned at pages 40-41,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice.* Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

Not only were both statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care, but they were misleading. They demonstrate that Tricida was aware of the risk posed by using clinical data from a patient population outside the United States that is materially different from the United States patient population, and they demonstrate that Tricida was aware of the risk posed by majority enrollment in Eastern European sites. Yet, Tricida omitted to reveal that its Phase 3 TRCA-301 trial was conducted using a patient population mostly from Eastern Europe—which the FDA does not consider to be applicable to a United States patient population under the circumstances—and that trial enrollment was concentrated at one site, making the risk disclosure not only ineffective but false and misleading.

Materially False and Misleading Statements and Omissions Concerning the Second and Third Quarters of 2018

61. On August 9, 2018, Tricida filed its Form 10-Q for the second quarter of 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2Q18 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

62. On November 8, 2018, Tricida filed its Form 10-Q for the third quarter of 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2Q18 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

63. The risk disclosures in both the 2Q18 10-Q and 3Q18 10-Q stated,

> *We recently completed a* randomized, double-blind, placebo-controlled, *multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301*. The TRCA-301 trial enrolled 217 CKD patients with metabolic acidosis. Eligible subjects who completed the 12-week treatment period in our pivotal Phase 3 trial were invited to continue in our 40-week safety extension trial, TRCA-301E.
>
> * * *
>
> *Our safety extension trial, TRCA-301E, is being conducted at 29 sites in the United States and Europe*.

64. The statements identified in italics above were false and misleading. These statements were materially false and misleading when made for two reasons, and Defendants knew, or recklessly disregard the truth in making these statements. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, one site in particular was disproportionately responsible for enrollment—both material pieces of

information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these details was material and stating that the TRCA-301E trial was conducted "at 29 sites in the United States and Europe" was materially misleading for the reasons stated in ¶¶56-57.

65. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 10-Qs cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Qs warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice*. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For reasons stated in ¶60, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading.

Materially False and Misleading Statements and Omissions Concerning the Full Year 2018 and the Second Public Offering

66. On March 29, 2019, Tricida filed its Form 10-K for the full year 2018, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 2018 10-K, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Annual Report on

Form 10-K of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

67. On April 3, 2019 Tricida filed a Form S-1MEF and related Rule 424(b)(4) Prospectus in connection with the Company's secondary offering, both of which were signed by Defendant Klaerner.

68. The "Business" section of the 2018 10-K and April 2019 Prospectus stated, "In May 2018, we completed our pivotal Phase 3 clinical trial, TRCA-301, and in March 2019, the results of this trial were published in The Lancet.… *We conducted the trial at 47 sites in the United States and Europe*, of which 37 sites enrolled patients." The risk disclosures in the 2018 10-K and April 2019 Prospectus stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for TRC101, known as TRCA-301.… *Our extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe*."

69. The statements identified in italics above were false and misleading. These statements were materially false and misleading when made for two reasons, and Defendants knew, or recklessly disregarded the truth in making this statement. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, one site in particular was disproportionately responsible for enrollment—both material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was material to investors, and stating that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" and the TRCA-301E trial was conducted "at 37 sites in the United States and Europe" rendered the statements materially misleading for the reasons stated in ¶¶56-57.

70. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2018 10-K and April 2019 Prospectus cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do

not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-K and Prospectus warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice*. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶60, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading.

71. The "Business" section of the 2018 10-K and April 2019 Prospectus also discussed the sample size of the VALOR-CKD trial:

> *We had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial* and initiated the trial in late 2018 in the United States and other countries *with an anticipated sample size of approximately 1,600 subjects*.
>
> * * *
>
> *We anticipate that the VALOR-CKD trial will randomize approximately 1,600 subjects* in order to show a 30% to 35% reduction in renal events, defined for purposes of the VALOR-CKD trial as a ≥ 40% reduction in eGFR, ESRD or renal death.
>
> * * *
>
> *Based on the magnitude of the increase in blood bicarbonate observed in our pivotal Phase 3 trial, TRCA-301, and the inverse relationship between*

> *blood bicarbonate and risk of renal events described by the Predictive MA Model, we have determined that randomizing 1,600 subjects* to TRC101 or placebo in a 1:1 ratio will result in 90% power to show a 30% to 35% reduction in renal events in the VALOR-CKD trial.

72. The statements identified in italics above were false and misleading. The statements that Tricida had determined 1,600 subjects to be the necessary number of patients for the VALOR-CKD confirmatory trial was false when made, and Defendants knew or recklessly disregarded the truth in making the statement. Regardless of what Tricida had previously anticipated the necessary VALOR-CKD patient enrollment to be, by March 2019 Tricida had set a target internally of enrolling 4,000 patients in the VALOR-CKD trial, according to CW1. The ADL disclosed by Tricida on February 25, 2021 confirmed the inadequacy of a 1,600-subject VALOR-CKD trial. One of the NDA's deficiencies identified by the FDA was the underpowered state of the VALOR-CKD trial: "The OND also concluded that the confirmatory trial, VALOR-CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial." Given that Tricida had committed in prior SEC filings to "obtain[ing] the FDA's agreement and finaliz[ing] the design of our confirmatory postmarketing trial, VALOR-CKD, and completely enroll[ing] or nearly completely enroll[ing] our confirmatory postmarketing trial, VALOR-CKD- prior to the submission of an NDA," the most reasonable inference to draw is that Tricida and Klaerner falsely represented the VALOR-CKD sample size to be lower than it needed to be. They had a motive to lie: Tricida was struggling to recruit enough patients for the confirmatory trial, but the Company had repeatedly told investors that the NDA would be filed in the second half of 2019. Tricida would not be able to appear to have nearly fully enrolled the VALOR-CKD trial in time with an unobtainable target enrollment.

73. Tricida and Klaerner knew, or recklessly disregarded, that the statements were false when made. First and foremost, Tricida set the enrollment target of 4,000 subjects. Additionally, Klaerner was intimately acquainted with the enrollment details. According to CW1, Klaerner was infuriated by the slow pace at which subjects were being enrolled in the

VALOR-CKD trial, and, at meetings attended by CW1 in June 2019, "screamed" at PRA employees for failing to recruit enough patients. The false statements about the VALOR-CKD trial's sample size were material because they misrepresented the VALOR-CKD trial to be adequately powered to confirm the TRCA-301/TRCA-301E's findings with clinical evidence of efficacy. This, in turn, concealed the actual risk that the FDA would reject the veverimer NDA.

Materially False and Misleading Statements and Omissions Concerning First Quarter of 2019

74. On May 10, 2019, Tricida filed its Form 10-Q for the first quarter of 2019, which was signed by Defendant Klaerner. Klaerner certified in Exhibit 31.1 to the 1Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

75. The risk disclosures in the 1Q19 10-Q stated,

> In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.
>
> * * *
>
> Our 40-week extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe.
>
> * * *
>
> We had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial and initiated the trial in late 2018 in the United States and other countries *with an anticipated sample size of approximately 1,600 subjects*.

76. The statements identified in italics above were false and misleading. These statements were materially false and misleading when made for three reasons, and Defendants knew or recklessly disregarded the truth in making these statements. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically; second, one site in particular was disproportionately responsible for enrollment; and third, Tricida needed 4,000 subjects to

adequately power the VALOR-CKD trial—all material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was accordingly material to investors. Stating that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" and the TRCA-301E trial was conducted "at 37 sites in the United States and Europe" rendered the statements made materially misleading for the reasons stated in ¶¶56-57. For the reasons stated in ¶¶72-73, the statements that Tricida had determined 1,600 subjects to be the necessary number of patients for the VALOR-CKD confirmatory trial was false when made, and Defendants knew or recklessly disregarded the truth of it.

77. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 1Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice*. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶60, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading.

Materially False and Misleading Statements and Omissions at the Goldman Sachs Global Healthcare Conference

78. On June 12, 2019, Defendant Klaerner spoke at the Goldman Sachs Global Healthcare Conference:

> Graig Suvannavejh Goldman Sachs Group Inc., Research Division – Executive Director & Senior Equity Research Analyst:
>
> I think it's fascinating. So veverimer is your lead program. And it's -- how would you describe what's unique about that? And maybe that transition to kind of the clinical data that you've generated for that program?
>
> Gerrit Klaerner Tricida, Inc. – Founder, President, CEO & Executive Director:
>
> Yes. Let's start with the most recent news, which, in my career, I've never experienced. We set out to do a 1-year extension study, where we hope to see good safety, which we did. We hoped to see continued durable effect of our surrogate marker, which is basically the increase of serum bicarbonate. And on top of it, in this blinded placebo-controlled study, we actually saw a reduced all-cause mortality, reduced number of patients requiring dialysis and fewer patients having -- losing 50% of the kidney function.
>
> *And when you fast-forward in all the work that we've done, from a discovery to an early development, to a late stage development, agreeing with FDA, an accelerated approval path, you -- all you expect to do is to show a surrogate effect, and then you have a post-marketing commitment that ultimately then, you confirm that, that surrogate is going to translate.*
>
> *Now we found ourselves with 1-year safety extension data that showed clinical benefit*. And I think that excitement, you can feel now, I think, in the company, both from interacting with payers, interacting with physicians, interacting with regulators, I think that is a good thing to have.
>
> Suvannavejh, Goldman Sachs:
>
> And I'm going to assume that as you saw that data, I know it's surprising. What's the reaction that you have maybe gotten from the physician community just about some of these findings?
>
> Klaerner:
>
> It's interesting. I've worked in the renal space for 20 years, and we've tried. When it comes to hyperphosphatemia, people have tried to show that

controlling serum phosphorus in these patients is going to translate to improved outcomes. It doesn't.

People have tried to show that for anemia or for hyperkalemia. In the end, all those are just complications, where the nephrologist is, in a way, doomed to just tinker with those parameters in order to keep the patient stable until they inevitably need dialysis, or quite frankly, they're more likely to die, unfortunately.

And it's really been since the RAS inhibitor trials, the (inaudible) trials since the late '90s, where there's been a disease-modifying agent. And for our thought leaders and even community physicians to have data now, even though it's a small trial, it's a 200-patient trial, but it is a gold standard, double-blind, placebo-controlled.

And to see a 65% reduction in the time to event of, as I pointed out, all-cause mortality, dialysis or 50% eGFR reduction, we call it DD50. That is much needed in this field, in a field that has not seen a lot of progress and, unfortunately, a lot of failures.

We have -- one of our very famous thought leaders, who's [done developing] the SGLT2 inhibitor trials, he goes to our investigator meetings, and he shows a tombstone with all the feared outcome trials in renal. And that's the unfortunate reality in this field. And so to have the first study now that in this advanced population with multiple co-morbidities to show improved outcomes has created a real jolt in this nephrology community.

Suvannavejh, Goldman Sachs:

So you've got another study ongoing, VALOR-CKD. Tell us how it kind of fits in the overall strategy of developing veverimer?

Klaerner:

It's a study that is now a post-marketing commitment with FDA following the accelerated approval path. That's something that is quite common for oncology or orphan diseases. It's not very common for cardiorenal.

We have the ability to submit our NDA with just one pivotal trial that shows a surrogate effect, and we've completed that. The pivotal portion of that trial actually just got published in the Lancet in March, and we submitted the extension study to another major medical journal and hope to see that published soon, too.

We -- under that accelerated approval path, we obviously have a post-marketing commitment to show that our surrogate is going to translate to clinical benefit. *And the VALOR-CKD study is a time-to-event study with 1,600 patients that is a one-to-one randomized double-blind study*. We're conducting it in all over the world, in 33 countries and up to 350 sites. And it's underway. And we hope to -- and we are on track to really have this sufficiently recruited to submit our NDA in the second half of this year.

> Suvannavejh, Goldman Sachs:
>
> And what would you ideally hope to get out of that study?
>
> Klaerner:
>
> Ultimately, the study is powered to show a 30% reduction in renal progression, as measured in a slightly different endpoint, DD40. So it's renal death, dialysis and 40% eGFR reduction. *And again, with 1,600 subjects, 800 on active, 800 on placebo, we control a 30% reduction in the time to that event*.

79. The statements identified in italics above were false and misleading. Klaerner knew these statements to be false and misleading or was reckless is his disregard for the truth when he made them.

80. First, Klaerner materially misrepresented that approval through the ADA is somehow simpler and easier than approval along the standard path because "all you expect to do is to show a surrogate effect, and then … you confirm that, that surrogate is going to translate." But there is nothing easier about shepherding drug candidates through the accelerated approval process. Drug candidates evaluated via the ADA must still meet the same statutory standards for safety and efficacy: substantial evidence based on adequate and well-controlled clinically investigations. *See* Richard Moscicki, M.D., *FDA's Breakthrough Therapy Designation and Expedited Review Programs: Part II*, FDA (Apr. 21, 2016), https://www.fda.gov/drugs/news-events-human-drugs/fdas-breakthrough-therapy-designation-and-expedited-review-programs-part-ii; 21 U.S.C. § 355(d); 21 C.F.R. § 314.126. And Drugs granted accelerated approval must promptly conduct post-marketing confirmatory trials to verify clinical benefit, all of which dictates a more rapid pace of development. Moscicki, *FDA's Expedited Review Programs*, *supra*. The related time crunch was evident in Tricida's inability to adequately recruit their VALOR-CKD trial prior to the pre-planned NDA submission window. Moreover, where the surrogate endpoint itself has yet to be accepted by the FDA as reasonably likely to demonstrate clinical efficacy, the drug sponsor faces the additional obstacle of convincing the FDA that the chosen surrogate endpoint is clinically relevant. If anything is to be said about the ADA, it is that the ADA presents more obstacles towards approval than the traditional path, not fewer.

81. Further complicating matters, Tricida was proceeding through the ADA with only a single Phase 3 efficacy trial, which, for the reasons stated in ¶56-57, Tricida knew would receive enhanced scrutiny from the FDA. This information was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval, and its omission from the statement suggesting that approval along the ADA is easier than the traditional approval path further enhanced the false and misleading nature of the statement.

82. Klaerner knew or recklessly disregarded that the statement was false when he made it. He is an experienced clinical stage pharmaceutical company executive, having founded two clinical stage companies prior to Tricida—one of which (Ilypsa) was acquired by Amgen, Inc. and the other of which (Relypsa) went public before being acquired by Galencia Ltd. In his own words, he's "done this now 3 times," taking "an idea … to a commercial product." Moreover, the FDA guidance establishing higher scrutiny for single study phase 3 trials has been unchanged for over two decades.

83. Second, Klaerner misleadingly presented the single phase 3 efficacy trial as a strength—something increasing the likelihood that the FDA would approve veverimer— when in fact it was a significant risk to FDA approval of the NDA. For the reasons stated in ¶57, Tricida knew that the TRCA-301/TRCA-301E trial would receive enhanced scrutiny from the FDA. Klaerner's statement presenting the submission of an NDA based on a single pivotal trial to be an accomplishment was, accordingly, false and misleading. It was materially so because it inflated the investing public's perception of the likelihood that veverimer would receive FDA approval.

84. Finally, for the reasons stated in ¶¶72-73, Klaerner's statement that Tricida had determined 1,600 subjects to be the necessary number of patients for the VALOR-CKD confirmatory trial was false when made, and Defendants knew or stated this in reckless disregard for the truth.

Materially False and Misleading Statements and Omissions Concerning the Second Quarter of 2019

85. On August 9, 2019 Tricida filed its Form 10-Q for the second quarter of 2019, which was signed by Defendant Klaerner.

86. Klaerner certified in Exhibit 31.1 to the 2Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

87. The risk disclosures in the 2Q19 10-Q stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301…. Our 40-week extension trial, TRCA-301E, *was conducted at 37 sites in the United States and Europe*."

88. The statements identified in italics above were false and misleading. These statements were materially false and misleading when made for two reasons, and Defendants knew, or recklessly disregarded the truth in making these statements. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, one site in particular was disproportionately responsible for enrollment—both material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was material, and stating that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" and the TRCA-301E trial was conducted "at 37 sites in the United States and Europe" rendered that statements materially misleading for the reasons stated in ¶¶56-57.

89. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and

efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice.* Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶60, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading.

Materially False and Misleading Statements and Omissions Concerning the Third Quarter of 2019

90. On November 14, 2019 Tricida filed its Form 10-Q for the third quarter of 2019, which was signed by Defendant Klaerner.

91. Klaerner certified in Exhibit 31.1 to the 3Q19 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

92. The risk disclosures in the 3Q19 10-Q stated,

> In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301.
>
> * * *
>
> Our TRCA-301 trial *was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe*.
>
> * * *
>
> We anticipate *the VALOR-CKD trial will randomize approximately 1,600 subjects* and is currently estimated to complete enrollment in mid-2020.

93. The statements identified in italics above were false and misleading. These statements were materially false and misleading when made for three reasons, and Defendants knew or recklessly disregarded the truth in making these statements. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe; second, one site in particular was disproportionately responsible for enrollment; and third, Tricida needed 4,000 subjects to adequately power the VALOR-CKD trial—all material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was accordingly material to investors and rendered Klaerner's statements materially misleading. Stating that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" and the TRCA-301E trial was conducted "at 37 sites in the United States and Europe" rendered the statements made materially misleading for the reasons stated in ¶¶56-57. For the reasons stated in ¶¶72-73, the statements that Tricida had determined 1,600 subjects to be the necessary number of patients for the VALOR-CKD confirmatory trial was false when made, and Defendants knew or recklessly disregarded the truth of it.

94. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 3Q19 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this

> is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice.* Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶60, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading.

Materially False and Misleading Statements and Omissions Concerning the Fourth Quarter and Year 2019

95. On March 2, 2020, Tricida filed its Form 10-K for the year 2019, which was signed by Defendant Klaerner.

96. Klaerner certified in Exhibit 31.1 to the 2019 10-K, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Annual Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

97. The "Business" section of the 10-K stated,

> *We conducted the [TRCA-301] trial at 47 sites in the United States and Europe*, of which 37 sites enrolled patients.
>
> * * *
>
> *Based on the magnitude of the increase in serum bicarbonate observed in our pivotal Phase 3 trial, TRCA-301, and the inverse relationship between*

> *serum bicarbonate and risk of renal events described by the Predictive MA Model, we have determined that randomizing 1,600 subjects* to veverimer or placebo in a 1:1 ratio will result in 90% power to show a 30% to 35% reduction in renal events in the VALOR-CKD trial.

98. The risk disclosures stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301…. *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe*."

99. The statements identified in italics above were false and misleading. These statements were materially false and misleading when made for three reasons, and Defendants knew or recklessly disregarded the truth in making these statements. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically; second, one site in particular was disproportionately responsible for enrollment; and third, Tricida needed 4,000 subjects to adequately power the VALOR-CKD trial—all material pieces of information for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was accordingly material to investors. Stating that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" and the TRCA-301E trial was conducted "at 37 sites in the United States and Europe" rendered the statements made materially misleading for the reasons stated in ¶¶56-57. For the reasons stated in ¶¶72-73, the statements that Tricida had determined 1,600 subjects to be the necessary number of patients for the VALOR-CKD confirmatory trial was false when made, and Defendants knew or recklessly disregarded the truth of it.

100. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 2019 10-K cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-K warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials

> should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice.* Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶60, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading.

Materially False and Misleading Statements and Omissions Concerning the First Quarter of 2020

101. On May 7, 2020, Tricida held its 1Q20 earnings call with analysts. During the call, Klaerner stated,

> In our Day 74 letter, the FDA indicated that they plan to hold an advisory committee meeting or AdCom to discuss the application. *In our late-cycle meeting with the FDA held in May 2020, the FDA indicated it currently does not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19. In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues.* We presented our data and rationale as to why we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.
>
> Under the initial approval, we have to ensure that US patients who would be prescribed veverimer get clinically significant benefit that outweighs the risk of treatment. *Overall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program.*

102. The statements identified in italics above were false and misleading. Klaerner made multiple false and misleading statements on the May 7, 2020 conference call by failing to disclose material information necessary to render the statements true in the context in which they were made. First, the reason why the FDA "indicated it currently does not plan to hold an AdCom to discuss veverimer" was not, primarily, due to the logistical challenges posed by COVID-19, but instead due to the FDA's concerns that there were too many problems with the NDA to even warrant convening an Advisory Committee. Plus, by discussing the data underling the clinical trial and the "outstanding clinical review issues" Klaener misled investors by omitting to reveal the FDA's concerns regarding the trial data supporting TRCA-301, that the majority of participants were from Eastern Europe and the high concentration in one trial site. Tricida confirmed as much in its 2Q20 10-Q, filed August 6, 2020, in which the Company disclosed,

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.

Given the magnitude of these issues, the Company said in the 2Q20 10-Q that it was likely to receive a CRL. These review issues proved to be the main reasons for the FDA's rejection of veverimer, as the Company finally spelled out in a February 25, 2021 press release titled "Tricida Has Received an Appeal Denied Letter from the Office of New Drugs of the FDA in Response to its Formal Dispute Resolution Request":

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression. The OND also concluded that the confirmatory trial, VALOR-CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial.
>
> The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND

> noted concerns around the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

103. Klaerner either knew, or recklessly disregarded, that these issues presented a significant obstacle to the approval of veverimer, and—given that they were the focus of discussion at the May 2020 late-cycle meeting—it was misleading for Klaerner to suggest that logistical complications caused by COVID were the main reason for the FDA's decision to cancel the Advisory Committee. His false statement was material because it concealed the true risk that the FDA would reject the veverimer NDA.

104. On May 8, 2020, Tricida filed its Form 10-Q for the first quarter of 2020, which was signed by Defendant Klaerner.

105. Klaerner certified in Exhibit 31.1 to the 1Q20 10-Q, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, that he had "reviewed this Quarterly Report on Form 10-Q of Tricida, Inc." and that "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

106. The risk disclosures section stated, "In May 2018, *we completed our multicenter*, randomized, double-blind, placebo-controlled, *pivotal Phase 3 clinical trial* for veverimer, known as TRCA-301…. *Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe*."

107. These statements were materially false and misleading when made for two reasons, and Defendants either knew, or recklessly disregarded, them to be so. First, most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, and second, one site in particular was disproportionately responsible for enrollment—both material facts for an investor to be able to accurately assess the likelihood that veverimer would receive FDA approval. The omission of these facts was material to investors, and stating that the TRCA-301

trial was conducted "at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe" and rendered the statements made materially misleading for the reasons stated in ¶¶56-57.

108. Tricida also demonstrated its knowledge of the falsity and materiality of these statements through the included risk disclosures. The 1Q20 10-Q cautioned that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Similarly, the 10-Q warned,

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice*. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> *We conducted the TRCA-301 trial, the extension trial, TRCA-301E, and the VALOR-CKD trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data*, and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

For the reasons stated in ¶60, these italicized statements were too generalized to disclaim the specific risk at issue but demonstrate Defendants' knowledge of the specific risk and were actually false and misleading.

THE TRUTH BEGINS TO EMERGE

109. On July 15, 2020, after the close of trading, Tricida issued a press release revealing that the FDA notified Tricida on July 14, 2020 that the Agency had "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." Tricida said the notification did not "specify the deficiencies identified by the

FDA," but "[t]he Company plans to work with the FDA to identify and seek to resolve the deficiencies." Klaerner was quoted in the press release, stating "We are surprised and disappointed by this news …. We continue to believe in the potential of veverimer to be disease modifying and our goal is to work with FDA to identify and resolve the issues in order to bring veverimer to patients."

110. In response to this news, the price of Tricida common stock fell $10.56 per share to close at $15.64 per share on July 16, 2020.

111. The July 15, 2020 press release publicly revealed for the first time that there were issues with the veverimer NDA, but Defendants still withheld material information from the investing public. Tricida and Klaerner were well aware of the deficiencies referenced by the FDA, i.e., that the majority of trial sites were in Eastern Europe and one site in particular was disproportionately responsible for the trial's enrollment. They had just met with the FDA in May 2020 for a late-cycle review, during which the FDA specifically raised concerns about the ability of the surrogate endpoint for the TRCA-301/TRCA-301E trial to demonstrate likely clinical effect as well as the comparability of the trial subjects to the U.S. patient population and U.S. medical practice. Moreover, these had been long-standing points of discussion with the FDA throughout the clinical trials. Tricida and Klaerner also knew (and had long known) that the VALOR-CKD trial was underpowered to demonstrate the effect predicted by the TRCA-301 trial, having internally set a target of enrolling 4,000 subjects. And Defendants also knew that an NDA supported by a phase 3 program consisting of only a single pivotal trial, such as the veverimer NDA, would receive heightened scrutiny from the FDA. The press release indicated that the NDA would not be approved by the PDUFA date, but the details would have made clear that the NDA was nowhere near approval—i.e., it could not be salvaged by a short-term fix. The failure to mention these facts withheld key pieces of the whole truth.

112. On August 24, 2020, at 8:30 am, prior to the opening of trading, Tricida issued a press release announcing that it [had] received a Complete Response Letter ("CRL") from the FDA for its veverimer NDA on August 21, 2020:

> According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit. There were no safety, clinical pharmacology/biopharmaceutics, CMC or non-clinical issues identified in the CRL.
>
> The CRL provided multiple options for resolving the identified deficiencies. In order to obtain approval for veverimer the company may or may not have to conduct an additional clinical trial. The FDA indicated it is willing to meet with Tricida to discuss options for obtaining approval, including under the Accelerated Approval Program.
>
> "We have collaborated with the FDA on the Accelerated Approval Program for veverimer and while we are disappointed to receive this CRL, we are pleased that the FDA has provided helpful, specific comments and indicated their willingness to continue to work with us to pursue approval of veverimer," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We remain confident in the fundamentals of, and unmet medical need for, veverimer and we continue to conduct our confirmatory trial, VALOR-CKD." Tricida plans to request a Type A meeting with the FDA in the coming weeks. A Type A meeting is usually scheduled within 30 days of the meeting request. Following the Type A meeting, anticipated early in the fourth quarter, Tricida plans to provide an update on next steps and estimated timing of a potential resubmission of the NDA.

113. Tricida's stock price fell by $3.13 per share, or 24% on this news, falling from its prior closing price of $13.24 per share to close at $10.11 per share on August 24, 2020.

114. The August 24, 2020 press release revealed for the first time the FDA's position that the Phase 3 TRCA-301/TRCA-301E trial was inadequate on its own to demonstrate the efficacy of veverimer. It also revealed that the FDA required additional data regarding the applicability of the observed treatment effect to the U.S. population. However, the press release went to great lengths to temper the true nature of these issues by suggesting that there were no severe obstacles to near-term approval and emphasizing (1) the "multiple options for resolving the identified deficiencies," (2) Klaerner's pleasure about the FDA's feedback, and (3) the Company's confidence in the "fundamentals" of veverimer, such that the VALOR-CKD trial was continuing unchanged. The press release failed to mention the numerous issues specific to

having relied upon a single pivotal Phase 3 trial, said nothing of the underenrolled/underpowered nature of the VALOR-CKD trial and otherwise hid the severity of the issues that it did share.

115. On October 29, 2020, Tricida announced that during an End-of-Review Type A conference held October 20, 2020 with the FDA's Division of Cardiology and Nephrology—which had issued the CRL on August 21, 2020 denying Tricida's veverimer NDA—the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." But because the Tricida could not provide this interim information from the VALOR-CKD trial "without compromising the integrity of the ongoing trial," additional trials would be required to gather this information. In other words, the FDA rejected the veverimer NDA because Tricida had failed to demonstrate that the single phase 3 trial's surrogate endpoint could reasonably predict clinical efficacy. Tricida suggested that this was the first time the FDA had called into question Tricida's use of serum bicarbonate to measure efficacy, noting that the Company's discussions with the FDA over nearly four years "focused on development of veverimer based solely on the use of serum bicarbonate as the surrogate endpoint to enable accelerated approval, with CKD progression data to be provided only at the completion of the VALOR-CKD trial." The same press release disclosed that Tricida was "significantly reducing its headcount from 152 to 59 people and will discuss its commitments with vendors and contract service providers to potentially provide additional financial flexibility."

116. In response to this news, Tricida's stock price fell $3.90 per share, to close at $4.37 per share on October 29, 2020.

117. The October 29, 2020 press release revealed for the first time that Tricida would have to provide clinical evidence of CKD progression (instead of just chemical evidence of serum bicarbonate levels), and that that evidence would have to come from the VALOR-CKD trial or some other yet-to-be designed trial. However, acquiring that evidence from the VALOR-CKD trial would eliminate its ability to function as a confirmatory postmarketing trial for purposes of the accelerated approval process. The press release still said nothing about either the

numerous issues specific to having relied upon a single pivotal Phase 3 trial or the under-enrolled/underpowered nature of the VALOR-CKD trial, which, if revealed, would have made clear that the VALOR-CKD trial was not an adequate confirmatory postmarketing trial anyways. Although the announced reduction in headcount suggested that near-term commercialization of veverimer was not likely, the press release emphasized that there was still a path forward because the company "plans to wait for formal meeting minutes from the FDA related to the End-of-Review Type A meeting prior to determining how to proceed with obtaining regulatory approval for veverimer."

118. On December 8, 2020, sixteen minutes before trading closed for the day, Tricida announced that it had revised the protocol for the VALOR-CKD trial to replace an "adaptive design" and "interim analysis for sample size adjustment" with "a group sequential design" and "an unblinded interim analysis for early stopping for efficacy." Tricida had scrapped plans providing any semblance of near-term approval prospects for veverimer. The press release also provided an update on the regulatory status of the veverimer NDA:

> A Formal Dispute Resolution Request (FDRR) has been submitted to the FDA to seek clarity on the path forward for resubmitting our New Drug Application (NDA) through the Accelerated Approval Program. The FDRR requests that the Office of New Drugs (OND) find that the magnitude of serum bicarbonate change seen in the TRCA-301 and TRCA-301E trials is reasonably likely to predict clinical benefit in the treatment of metabolic acidosis associated with CKD and that it can therefore serve as the basis for accelerated approval. If accepted for consideration, a decision on the FDRR is expected in the first quarter of 2021. The timing and next steps for a resubmission of the NDA for veverimer will be dependent upon the OND's decision.
>
> "We believe that we are studying the right patient population and the right CKD progression endpoint in VALOR-CKD. Hence, we believe that an adaptive design is no longer necessary and have locked in the sample size at 1,600 subjects and built in two opportunities for stopping early for efficacy over the next 18 to 24 months, in the event that the effect of veverimer on slowing CKD progression is greater than currently modeled," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "And while we are disappointed that we could not come to a resolution with the Division of Cardiology and Nephrology on the resubmission of our NDA during our Type A meeting, we believe that the

> focused, single issue FDRR currently represents the best approach to bring veverimer to patients through accelerated approval."

119. The press release, like earlier press releases, focused on one issue with the NDA: the surrogate endpoint's ability to predict clinical benefit. This time, the press release presented a new way—the FDRR—for the FDA to approve the NDA. Importantly, the press release still said nothing about either the numerous issues specific to having relied upon a single pivotal Phase 3 trial or the under-enrolled/underpowered nature of the VALOR-CKD trial, instead highlighting the "locked in sample size [of] 1,600 subjects" for the VALOR-CKD trial and two new "opportunities for stopping early for efficacy over the next 18-24 months …." Tricida's stock price fell from its closing price of $8.12 per share on December 8, 2020 to close at $6.68 per share on December 9, 2020, an almost 18% decline.

120. Twenty-five minutes before markets closed on February 25, 2021, Tricida announced in a press release that the Company had "received an Appeal Denied Letter (ADL), from the Office of New Drugs (OND) of the FDA in response to its Formal Dispute Resolution Request (FDRR) submitted in December 2020." According to Tricida, the FDA's ADL said the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," and "the confirmatory trial, VALOR-CKD, is underpowered …." The press release also publicly revealed for the first time the FDA's "concerns that are particularly relevant in an NDA supported by a single registration trial": the trial results were "strongly influenced by a single site," and "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population." This press release finally revealed the numerous deficiencies plaguing the veverimer NDA, all of which the Company had known about long before it even submitted the NDA.

121. On this news, Tricida's stock price fell from $7.36 per share at close on February 25, 2021 to $5.11 per share at close on February 26, 2021.

ADDITIONAL ALLEGATIONS OF SCIENTER

122. Throughout the class period, Defendant Klaerner sold nearly $10 million in shares of Tricida stock. When he made these sales of Tricida stock, he was privy to the complete—and nonpublic—collection of risks related to the veverimer NDA's likelihood for FDA approval. He knew that his and Tricida's failure to disclose the full risk profile for veverimer's FDA review had inflated the value of Tricida stock. He has only made a single purchase of Tricida stock (ever), which occurred on July 2, 2018. He purchased 15,790 shares at a price of $19.00 apiece. He made 34 sales of Tricida stock between December 26, 2018 and February 8, 2021, totaling $9,758,875. His sales were particularly aggressive from March 28, 2019—days before the secondary public offering—and December 18, 2019—while the hype of the recently-filed veverimer NDA remained fresh—during which period Tricida's stock consistently traded at prices between $30 and $43.50 per share. His trades during the class period were as follows:

Date	Transaction	Share Price	Shares Traded	Sum
02/08/21	Sell	$7.26	8,000	$58,080
01/13/21	Sell	$7.39	16,690	$123,292
01/12/21	Sell	$7.65	9,821	$75,131
01/11/21	Sell	$7.49	21,489	$160,953
07/15/20	Sell	$26.33	4,000	$105,320
07/01/20	Sell	$27.15	4,000	$108,600
06/15/20	Sell	$25.97	4,000	$103,869
06/01/20	Sell	$26.23	4,000	$104,920
05/15/20	Sell	$31.55	4,000	$126,220
05/01/20	Sell	$27.98	4,000	$111,906
04/15/20	Sell	$27.47	4,000	$109,891
04/06/20	Sell	$24.22	4,000	$96,880
03/16/20	Sell	$23.91	4,000	$95,640
03/02/20	Sell	$31.53	4,000	$126,120
02/18/20	Sell	$36.10	4,000	$144,400
02/03/20	Sell	$36.33	4,000	$145,330
01/15/20	Sell	$35.26	4,000	$141,040
01/02/20	Sell	$37.15	4,000	$148,607
12/18/19	Sell	$38.91	31,750	$1,235,457
12/11/19	Sell	$43.50	7,572	$329,346
12/10/19	Sell	$43.28	3,948	$170,869
12/01/19	Sell	$39.65	8,000	$317,160
11/01/19	Sell	$38.54	49,000	$1,888,556

10/28/19	Sell	$37.26	4,000	$149,035
10/01/19	Sell	$31.07	11,223	$348,663
09/30/19	Sell	$30.69	10,255	$314,734
08/28/19	Sell	$33.71	4,000	$134,840
07/29/19	Sell	$31.17	4,000	$124,680
07/06/19	Sell	$35.55	5,826	$207,097
07/03/19	Sell	$37.08	6,874	$254,854
03/28/19	Sell	$32.96	57,822	$1,905,974
03/04/19	Sell	$23.76	853	$20,267
03/01/19	Sell	$23.94	7,147	$171,064
12/26/18	Sell	$25.02	4,000	$100,080
07/02/18	Buy	$19.00	15,790	$300,010

Most of these trades occurred as part of a 10b5-1 plan, but this 10b5-1 plan was itself first implemented amidst Klaerner and Tricida's ongoing securities fraud (which began as of the IPO). Indeed, Tricida made materially false statements about the TRCA-301 trial before shares of the Company were even available to the investing public. Klaerner traded on the nonpublic knowledge of the inflated value of Tricida's stock throughout the class period.

123. Tricida itself engaged in insider trades through the initial public offering on June 28, 2018 and again in the secondary offering on April 3-8, 2019. Tricida needed funds to operate and continue its postmarketing trials of veverimer so it sold common stock to the investing public in its IPO. Thereafter, it was in need of additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA date in August 2020. Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018. At the time of the secondary offering, however, Tricida already knew of the significant risks in obtaining FDA approval for veverimer and failed to reveal these material facts to investors. Indeed, Tricida knew that most of the TRCA-301/301E trials had been conducted in Eastern Europe and that one trial site in particular had a disproportionate effect on the results, both of which severely undercut the credibility of the study results. Tricida and Klaerner knew at the time that the VALOR-CKD trial needed 4,000 subjects—not 1,600 subjects—to demonstrate the predicted clinical effect, but the Company was having a difficult time recruiting anywhere close to that number of patients for the trial. Tricida

sold 6.44 million shares of common stock, at $36 per share, for over $231 million by the time the secondary stock offering completed on April 8, 2019.

124. Tricida had only one drug candidate: veverimer. Accordingly, the day-to-day operations at the Company leading up and throughout the Class Period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization; the Company's entire future hung on the success of bringing veverimer to market. And Tricida was Klaerner's project through and through. He "started it in 2013 in his living room" shortly after "finishing up the Relypsa experience" and he "was looking for an opportunity to create something that is truly disease-modifying." Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is "very passionate about polymer chemistry," and demonstrates himself to be intimately familiar with the design and functionality of veverimer. Thus, Klaerner, as CEO was involved in and aware of even more than just the core operations at Tricida.

125. He was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. According to CW1, Klaerner attended numerous meetings about patient recruitment and enrollment for the VALOR-CKD trial. Klaerner also attended meetings with and inspections by the FDA. For example, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019 reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, Confidential Witness 2 ("CW2")—who served in the role of Executive Director of Operations from September 2019 through October 2020 and was responsible for overseeing the commercialization of veverimer after (hopeful) FDA approval—stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency. CW2 also stated that Klaerner was even specific about where he wanted to hold the veverimer launch party, insisting to CW2 that the party be held at the Ritz-Carlton Hotel at Half Moon Bay despite CW2's concern that such an expensive location might not please the FDA.

LOSS CAUSATION / ECONOMIC LOSS

126. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated the price of Tricida stock and operated as a fraud or deceit on Class Period purchasers of Tricida stock by misrepresenting and omitting material information about the design and execution of the TRCA-301/TRCA-301E and VALOR-CKD trials. When Defendants' prior misrepresentations and omissions were disclosed to the market, beginning on July 15, 2020, Tricida's stock price fell as the prior artificial inflation came out of the price. The full inflation did not come out of the stock price until February 25, 2021. As a result of their purchases of Tricida stock during the Class Period, Lead Plaintiff and other members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

127. Defendants' misleading statements and omissions of material facts, identified herein at ¶¶54-108, had the intended effect and caused Tricida stock to trade at artificially inflated prices during the Class Period.

128. As a direct result of the disclosures that began after the markets closed on July 15, 2020, as detailed in ¶¶109-11, Tricida's stock price suffered a significant decline. On July 16, 2020, the price of Tricida stock, which traded on NASDAQ, fell from the prior days close of $26.20 to a low of $15.64, a drop of 40.31% after the market learned that Tricida's veverimer NDA suffered from review issues that were significant enough to preclude discussions of labeling and postmarketing requirements/commitments.

129. In addition, the disclosure made before the markets opened on August 24, 2020, as detailed in ¶¶112-14, directly caused Tricida's stock price to fall. On August 24, 2020, Tricida's stock price fell from a close of $13.24 per share on August 21, 2020 to close at $10.11 per share—a drop of 23.64%—after learning that Tricida had received a CRL from the FDA in response to the veverimer NDA.

130. The disclosure before the markets opened on October 29, 2020, as detailed in ¶¶115-17, also had a direct impact on Tricida's stock price. The price of Tricida's stock plummeted from $8.27 at close on October 28, 2020 to $4.37 at close on October 29, 2020—a

drop of 47.16%—in direct response to additional disclosures regarding review issues with the veverimer NDA and its likelihood for near-term approval. Specifically, Tricida revealed that the FDA told Tricida that it was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would therefore "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program."

131. Tricida's stock price again suffered as a direct result of the disclosures made sixteen minutes before the markets closed on December 8, 2020, as detailed in ¶¶118-19, which revealed (1) that Tricida had failed to come to an agreement with the FDA on the resubmission of the veverimer NDA during the Type A meeting, (2) that the Company had filed a FDRR in an attempt to convince the FDA that the TRCA-301 trial results are reasonably likely to predict clinical benefit, and (3) that the Company had scrapped the protocol for the VALOR-CKD trial. In direct response, Tricida's stock price fell 17.73% from $8.12 per share at close on December 8, 2020 to close at $6.68 per share on December 9, 2020.

132. The final disclosures on February 25, 2021, as detailed in ¶¶120-21, directly caused Tricida's stock price to fall from $7.36 per share at close on February 25, 2021 to close at $5.11 on February 26, 2021—a drop of 30.57%. Twenty-five minutes before the markets closed on February 25, 2021, Tricida disclosed that it had received an ADL from the FDA, which determined (1) the "extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression," (2) "the confirmatory trial, VALOR-CKD, is underpowered," (3) the trial results were "strongly influenced by a single site," and (4) "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer," rendering questionable "the applicability to a U.S. patient population."

133. The declines in Tricida's stock price on July 16, 2020, August 24, 2020, October 29, 2020, December 8, 2020, and February 25, 2021 were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market.

134. The timing and magnitude of Tricida's stock price decline negates any inference that the losses suffered by Lead Plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific factors unrelated to Defendants' fraudulent conduct. On July 16, 2020, the Nasdaq was down only -0.7%, with the Nasdaq U.S. Smart Pharmaceuticals Index down even less, at -0.4%. On August 24, 2020, the Nasdaq increased 0.01%, and the Nasdaq Smart Pharma was down only -0.3%. On October 29, 2020, the Nasdaq increased 1.6% and the Nasdaq Smart Pharma increased 0.4%. On December 8, 2020, the Nasdaq decreased 0.02% and the Nasdaq Smart Pharma increased 1.46%. On February 25, 2021, the Nasdaq decreased 0.04%, while the Nasdaq Smart Pharma decreased -1.5%.

135. The losses suffered by Lead Plaintiff and other members of the Class were a direct result of Defendants' fraudulent scheme to inflate Tricida's stock price and the subsequent, significant declines in the value of that stock when Defendants' prior misrepresentations and omissions were revealed.

CLASS ACTION ALLEGATIONS

136. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), on behalf of a class consisting of all purchasers of the common stock of Tricida during the Class Period (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

137. The members of the Class are so numerous that joinder of them is impracticable. Throughout the Class Period, Tricida traded on the NASDAQ exchange. While the exact number of class members is not presently known to Lead Plaintiff, and can only be ascertained through discovery, Lead Plaintiff believes there are thousands of members in the proposed Class. Record owners and other members of the Class can be ascertained through records maintained by Tricida and/or its transfer agent. Those record holders could be notified of the pendency of this action by mail.

138. Lead Plaintiff's claims are typical of the claims of the members of the Class, as all are similarly affected by Defendants' wrongful conduct in violation of federal law.

139. Lead Plaintiff will fairly and adequately protect the interests of the members of the class and has retained competent and experienced securities litigation counsel.

140. Common questions of law and fact exist as to all members of the Class and will predominate over any questions solely affecting individual members of the Class. Among the common questions of law and fact common to the Class:

a. Whether the Exchange Act was violated by Defendants as alleged herein;

b. Whether statements made by Defendants misrepresented and omitted material facts about Tricida's business, operations, and management; and

c. To what extent the members of the Class have suffered damages, and the proper measure of those damages.

141. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, given that joinder of all members is impracticable. As the damages suffered by each individual Class member may be relatively small, the burden and expense of litigating individual cases would make it all but impossible for many members of the Class to redress wrongs done to them. There will not be any difficulty in managing this action as a class action.

FRAUD ON THE MARKET

142. Lead Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine. Among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. These omissions and material misrepresentations were material;

c. Tricida common stock traded in an efficient market throughout the Class Period;

d. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Tricida common stock; and

e. Lead Plaintiff and other members of the Class purchased Tricida common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

143. At all relevant times, the market for Tricida common stock was efficient, as:

a. Tricida filed periodic public reports with the SEC as a regulated issuer; and

b. Tricida regularly communicated with public investors via established communications mechanisms, including through the regular dissemination of press releases on major news wire services, communications through the financial press, securities analysts, the internet, and other similar reporting services.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

144. Plaintiffs incorporate ¶¶1-143 by reference.

145. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and concealed material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

146. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

147. Employed devices, schemes, and artifices to defraud;

148. Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

149. Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Tricida securities during the Class Period.

150. In addition to the duties of full disclosure imposed on Defendants as a result of their affirmative false and misleading statements to the public, the Exchange Act Defendants had a duty to promptly disseminate truthful information with respect to Tricida's operations and

performance that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including with respect to the Company's revenue and earnings trends, so that the market prices of the Company's securities would be based on truthful, complete, and accurate information. SEC Regulations S-X (17 C.F.R. §210.01, et seq.) and S-K (17 C.F.R. §229.10, et seq.).

151. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class have suffered damages in connection with their respective purchases of Tricida common stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Tricida securities and experienced losses when the artificial inflation was released from Tricida securities as a result of the revelations and prices decline detailed herein. Plaintiffs and the Class would not have purchased Tricida securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

152. By virtue of the foregoing, Tricida and Klaerner have each violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against Defendant Klaerner

153. Plaintiffs incorporate ¶¶1-143 by reference.

154. During his tenure as officer and director of Tricida, Klaerner and Tricida were controlling persons of the Company within the meaning of §20(a) of the Exchange Act. By reason of their positions of control and authority as officer and director of Tricida, Klaerner and Tricida had the power and authority to cause Tricida to engage in the conduct complained of herein. These defendants were able to, and did, control, directly and indirectly, the decision-making of Tricida, including the content and dissemination of Tricida's public statements and filings described herein, thereby causing the dissemination of the materially false and misleading statements and omissions as alleged herein. Tricida exercised control over and directed the actions of its senior managers, directors and agents, including Defendant Klaerner. Tricida controlled Defendant Klaerner and all of its employees and subsidiaries.

155. In his capacity as chief executive officer and director of Tricida, and as more fully described herein, Defendant Klaerner participated in the misstatements and omissions set forth above. Indeed, Klaerner had direct and supervisory involvement in the day-to-day operations of the Company and had access to non-public information regarding Tricida's deceptive and risky business practices. Defendants had the ability to influence and direct and did so influence and direct the activities of Defendants in their violations of §10(b) of the Exchange Act and Rule 10b-5 as detailed in ¶¶146-54.

156. As a result, Defendants were control persons within the meaning of §20(a) of the Exchange Act.

157. As set forth above, Tricida violated §10(b) of the Exchange Act. By virtue of its position, and as a result of its aforementioned conduct and culpable participation, Tricida is liable pursuant to §20(a) of the Exchange Act, jointly and severally with, and to the same extent as Defendant Klaerner is liable to Plaintiffs and the other members of the Class. Tricida exercised control over Klaerner and all of its employees and subsidiaries and, as a result of its aforementioned conduct and culpable participation, is liable pursuant to §20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Klaerner is liable to Plaintiffs and the other members of the Class.

158. This claim is brought within the applicable statute of limitations.

159. By reason of the foregoing, Defendants violated §20(a) of the Exchange Act, 15 U.S.C. §78(a).

June 1, 2021

Respectfully submitted,

/s/ Jeffrey C. Block

Jeffrey C. Block (*pro hac vice*)
Jacob A. Walker (SBN 271217)
Michael D. Gaines (*pro hac vice*)
BLOCK & LEVITON LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
(617) 398-5600 phone
jeff@blockleviton.com
jake@blockleviton.com

michael@blockleviton.com

Whitney E. Street (SBN 223870)
BLOCK & LEVITON LLP
100 Pine Street, Suite 1250
San Francisco, CA 94111
whitney@blockleviton.com

Addendum
Securities Fraud Claim Chart

No.	Speaker, Date, Medium	Statement	Why False / Misleading	Scienter Facts
Statements About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites				
A1	Tricida, 6/5/2018, Press Release	"The TRCA-301 double-blind, randomized, placebo-controlled Phase 3 trial was conducted at 47 sites in the United States and Europe."	As the sole pivotal Phase 3 trial for veverimer, TRCA-301/TRCA-301E was going to receive—and did receive—enhanced scrutiny from the FDA. The majority of trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe. Demonstrating that a pivotal trial is adequate and well controlled under 21 C.F.R. § 314.126 requires showing that any foreign data are applicable to the U.S. population and U.S. medical practice. FDA, *Acceptance of Foreign Clinical Studies*, *supra*, at 9; *see also* Stark, *Clinical Studies: Europe or the United States?*, *supra*. ("FDA's most common objection to European data is related to how representative European subjects are of the U.S. patient population."). But "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ significantly" compared with Western Europe, which is generally considered to be the	■ Regulations and well-established FDA guidance require foreign data to be applicable to the U.S. patient population and U.S. medical practice. ■ It is well established that "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ significantly" compared with Western Europe, which is generally considered to be the most U.S.-like foreign region besides Canada. ■ Klaerner knew the patient enrollment details for the TRCA-301/TRCA-301E trial. ■ Tricida was Klaerner's personal project, and he was involved in and aware of more than just the core operations at Tricida. He "started it in 2013 in his living room" shortly after "finishing up the Relypsa experience" and he "was looking for an opportunity to create something that is truly disease-modifying." Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is "very passionate about polymer chemistry," and demonstrates himself to be intimately familiar with the design and functionality of veverimer.
A2	Klaerner, 6/27/2018, IPO Rule 424(b)(4) Prospectus	"We conducted the [TRCA-301] trial at 47 sites in the United States and Europe."		
A3	Klaerner, 8/9/2018, 2Q18 10-Q	"Our safety extension trial, TRCA-301E, is being conducted at 29 sites in the United States and Europe."		
A4	Klaerner, 11/8/18, 3Q18 10-Q	"Our safety extension trial, TRCA-301E, is being conducted at 29 sites in the United States and Europe."		
A5	Klaerner, 3/29/2019, 2018 10-K	"We conducted the [TRCA-301] trial at 47 sites in the United States and Europe …. Our extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe."		
A6	Klaerner, 4/3/2019, Secondary Offering Rule 424(b)(4) Prospectus	"We conducted the [TRCA-301] trial at 47 sites in the United States and Europe …. Our extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe."		
A7	Klaerner, 5/10/2019,	"Our 40-week extension trial, TRCA-301E, was conducted at		

	1Q19 10-Q	37 sites in the United States and Europe."	most U.S.-like foreign region besides Canada. Sever, *A Roadmap for Optimizing Chronic Kidney Disease Patient Care*, *supra*. Thus, the fact that a majority of trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe, specifically, raised the risk that trial participants would not be sufficiently representative of the U.S. patient population and U.S. medical practice for the FDA to accept the trial results. This, in turn, was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. Accordingly, the omission of the fact that a majority of trial sites for the Phase 3 trial were in Eastern Europe from the statement that the TRCA-301 trial was conducted "at 47 sites in the United States and Europe" rendered it false and misleading.	■ Klaerner was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. According to CW1, Klaerner attended numerous meetings about patient recruitment and enrollment for the VALOR-CKD trial. Klaerner also attended meetings with and inspections by the FDA. For example, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019 reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, CW 2 stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency. CW2 also stated that Klaerner was even specific about where he wanted to hold the veverimer launch party, insisting to CW2 that the party be held at the Ritz-Carlton Hotel at Half Moon Bay despite CW2's concern that such an expensive location might not please the FDA. ■ Klaerner is an experienced clinical stage pharmaceutical company executive, having founded two clinical stage companies prior to Tricida—one of which (Ilypsa) was acquired by Amgen, Inc. and the other of which (Relypsa) went public
A8	Klaerner, 8/9/2019, 2Q19 10-Q	"Our 40-week extension trial, TRCA-301E, was conducted at 37 sites in the United States and Europe."		
A9	Klaerner, 11/14/2019, 3Q19 10-Q	"Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe."		
A10	Klaerner, 3/2/2020, 2019 10-K	"We conducted the [TRCA-301] trial at 47 sites in the United States and Europe …. Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe."		
A11	Klaerner, 5/8/2020, 1Q20 10-Q	"Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites in the United States and Europe."		

				before being acquired by Galencia Ltd. In his own words, he's "done this now 3 times," taking "an idea … to a commercial product." ■ Risk disclosures in the IPO Prospectus, secondary offering prospectus, and all 10-Qs and 10-Ks during the class period acknowledged, "The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice." ■ Risk disclosures in the IPO Prospectus, secondary offering prospectus, and all 10-Qs and 10-Ks during the class period warned, "We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data …." ■ These risk disclosures demonstrate that Tricida was aware of the risk posed by using clinical data from a patient population outside the United States that is materially different from the United States patient population, and they demonstrate that Tricida was aware of the risk posed by majority enrollment in Eastern European sites. ■ During the May 2020 late-cycle review, the FDA raised long-standing concerns about the comparability of the TRCA-301/TRCA-301E trial subjects to the U.S. patient population and U.S. medical practice.

				■ During the class period, Klaerner made 34 sales of Tricida stock, totaling $9,758,875. ■ Tricida needed funds to operate and carry out its postmarketing trial commitment, so it sold common stock to the investing public in the IPO. ■ Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018 and needed additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA date, so Tricida sold 6.44 million shares of common stock at $36 per share for over $231 million. ■ Tricida's future was entirely dependent on the success of brining veverimer to market: veverimer was Tricida's only drug candidate, so the day-to-day operations throughout the class period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization.
Risk Disclosures About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites				
B1	Klaerner, 6/27/2018, IPO Rule 424(b)(4) Prospectus	■ "The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice." ■ "We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future,	Both statements were too generalized to actually disclaim the specific risk inherent in relying upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care. These	■ Regulations and well-established FDA guidance require foreign data to be applicable to the U.S. patient population and U.S. medical practice. ■ It is well established that "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ

		conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data ….”	statements, in conjunction with the statements that the TRCA-301/TRCA-301E trial was conducted “in the United States and Europe,” suggests only that trial sites exist in Europe, generally—not Eastern Europe, specifically. Tricida omitted to reveal that its Phase 3 TRCA-301 trial was conducted using a patient population mostly from Eastern Europe—which the FDA does not consider to be applicable to a United States patient population under the circumstances—making the risk disclosure not only ineffective but false and misleading.	significantly” compared with Western Europe, which is generally considered to be the most U.S.-like foreign region besides Canada. ■ Klaerner knew the patient enrollment details for the TRCA-301/TRCA-301E trial. ■ Tricida was Klaerner’s personal project, and he was involved in and aware of more than just the core operations at Tricida. He “started it in 2013 in his living room” shortly after “finishing up the Relypsa experience” and he “was looking for an opportunity to create something that is truly disease-modifying.” Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is “very passionate about polymer chemistry,” and demonstrates himself to be intimately familiar with the design and functionality of veverimer. ■ Klaerner was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. According to CW1, Klaerner attended numerous meetings about patient recruitment and enrollment for the VALOR-CKD trial. Klaerner also attended meetings with and inspections by the FDA. For example, the Establishment Inspection Report for the inspection of Tricida’s South San Francisco facility
B2	Klaerner, 8/9/2018, 2Q18 10-Q	Same as above.		
B3	Klaerner, 11/8/18, 3Q18 10-Q	Same as above.		
B4	Klaerner, 3/29/2019, 2018 10-K	Same as above.		
B5	Klaerner, 4/3/2019, Secondary Offering Rule 424(b)(4) Prospectus	Same as above.		
B6	Klaerner, 5/10/2019, 1Q19 10-Q	Same as above.		
B7	Klaerner, 8/9/2019, 2Q19 10-Q	Same as above.		
B8	Klaerner, 11/14/2019, 3Q19 10-Q	Same as above.		
B9	Klaerner, 3/2/2020, 2019 10-K	Same as above.		
B10	Klaerner, 5/8/2020, 1Q20 10-Q	Same as above.		

				from December 9-17, 2019 reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, CW 2 stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency. CW2 also stated that Klaerner was even specific about where he wanted to hold the veverimer launch party, insisting to CW2 that the party be held at the Ritz-Carlton Hotel at Half Moon Bay despite CW2's concern that such an expensive location might not please the FDA. ■ Klaerner is an experienced clinical stage pharmaceutical company executive, having founded two clinical stage companies prior to Tricida—one of which (Ilypsa) was acquired by Amgen, Inc. and the other of which (Relypsa) went public before being acquired by Galencia Ltd. In his own words, he's "done this now 3 times," taking "an idea … to a commercial product." ■ Risk disclosures in the IPO Prospectus, secondary offering prospectus, and all 10-Qs and 10-Ks during the class period acknowledged, "The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice." ■ Risk disclosures in the IPO Prospectus, secondary offering prospectus, and all 10-Qs and 10-Ks during the class period warned, "We conducted the TRCA-301

				trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data ….” ■ These risk disclosures demonstrate that Tricida was aware of the risk posed by using clinical data from a patient population outside the United States that is materially different from the United States patient population, and they demonstrate that Tricida was aware of the risk posed by majority enrollment in Eastern European sites. ■ During the May 2020 late-cycle review, the FDA raised long-standing concerns about the comparability of the TRCA-301/TRCA-301E trial subjects to the U.S. patient population and U.S. medical practice. ■ During the class period, Klaerner made 34 sales of Tricida stock, totaling $9,758,875. ■ Tricida needed funds to operate and carry out its postmarketing trial commitment, so it sold common stock to the investing public in the IPO. ■ Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018 and needed additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA

				date, so Tricida sold 6.44 million shares of common stock at $36 per share for over $231 million. ■ Tricida's future was entirely dependent on the success of brining veverimer to market: veverimer was Tricida's only drug candidate, so the day-to-day operations throughout the class period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization.
Statements about the Multicenter Nature of the Phase 3 TRCA-301/TRCA-301E Trial				
C1	Tricida, 6/5/2018, Press Release	"Tricida … announced results from its pivotal Phase 3 double-blind, randomized, placebo-controlled, multi-center Phase 3 clinical trial, TRCA-301…."	As the sole pivotal Phase 3 trial for veverimer, TRCA-301/TRCA-301E was going to receive—and did receive—enhanced scrutiny from the FDA. FDA guidance makes clear that "[a] conclusion based on two persuasive studies will always be more secure than a conclusion based on a single, comparably persuasive study." FDA, *Providing Clinical Evidence of Effectiveness*, *supra*, at 13. "For this reason, reliance on only a single study will generally be limited to situations in which a trial has demonstrated a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome and confirmation of the result in a second trial would be practically	■ Well-established FDA guidance instructs that when a sponsor relies upon a single Phase 3 study, the FDA expects that single trial to be a large multicenter study in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen. ■ Tricida and Klaerner knew the patient enrollment details for the TRCA-301/TRCA-301E trial. ■ Tricida was Klaerner's personal project, and he was involved in and aware of more than just the core operations at Tricida. He "started it in 2013 in his living room" shortly after "finishing up the Relypsa experience" and he "was looking for an opportunity to create something that is truly disease-modifying." Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is
C2	Klaerner, 6/27/2018, IPO Rule 424(b)(4) Prospectus	"We recently completed a randomized, double-blind, placebo-controlled, multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301."		
C3	Klaerner, 8/9/2018, 2Q18 10-Q	"We recently completed a randomized, double-blind, placebo-controlled, multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301."		
C4	Klaerner, 11/8/18, 3Q18 10-Q	"We recently completed a randomized, double-blind, placebo-controlled, multicenter pivotal Phase 3 clinical trial for TRC101, known as TRCA-301."		
C5	Klaerner, 3/29/2019, 2018 10-K	"In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal		

		Phase 3 clinical trial for TRC101, known as TRCA-301."	or ethically impossible." *Id.* One of the characteristics the FDA looks for in a single study capable of supporting an effectiveness claim is "a large multicenter study in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen." *Id.* One trial site for the TRCA-301/TRCA-301E had been disproportionately enrolled, such that it could have had (and did have) a disproportionate impact on the favorable trial results. Accordingly, "the credibility of [its] multicenter study [was] diminished," *id.*, and therefore faced a significant uphill challenge to demonstrate effectiveness on its own (notwithstanding the statistically significant results observed in the trial). This information was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval. The omission of this information from the statement that the Phase 3 trial was "multi-center" rendered it materially false and misleading.	"very passionate about polymer chemistry," and demonstrates himself to be intimately familiar with the design and functionality of veverimer. ■ Klaerner was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. According to CW1, Klaerner attended numerous meetings about patient recruitment and enrollment for the VALOR-CKD trial. Klaerner also attended meetings with and inspections by the FDA. For example, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019 reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, CW 2 stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency. CW2 also stated that Klaerner was even specific about where he wanted to hold the veverimer launch party, insisting to CW2 that the party be held at the Ritz-Carlton Hotel at Half Moon Bay despite CW2's concern that such an expensive location might not please the FDA. ■ Klaerner is an experienced clinical stage pharmaceutical company executive,
C6	Klaerner, 4/3/2019, Secondary Offering Rule 424(b)(4) Prospectus	"In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial for TRC101, known as TRCA-301."		
C7	Klaerner, 5/10/2019, 1Q19 10-Q	"In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial for veverimer, known as TRCA-301."		
C8	Klaerner, 8/9/2019, 2Q19 10-Q	"In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial for veverimer, known as TRCA-301."		
C9	Klaerner, 11/14/2019, 3Q19 10-Q	"In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial for veverimer, known as TRCA-301."		
C10	Klaerner, 3/2/2020, 2019 10-K	"In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial for veverimer, known as TRCA-301."		
C11	Klaerner, 5/8/2020, 1Q20 10-Q	"Our TRCA-301 trial was conducted at 37 sites and our 40-week extension trial, TRCA-301E, was conducted at 29 sites		

		in the United States and Eu In May 2018, we completed our multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial for veverimer, known as TRCA-301."		having founded two clinical stage companies prior to Tricida—one of which (Ilypsa) was acquired by Amgen, Inc. and the other of which (Relypsa) went public before being acquired by Galencia Ltd. In his own words, he's "done this now 3 times," taking "an idea … to a commercial product." ■ During the class period, Klaerner made 34 sales of Tricida stock, totaling $9,758,875. ■ Tricida needed funds to operate and carry out its postmarketing trial commitment, so it sold common stock to the investing public in the IPO. ■ Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018 and needed additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA date, so Tricida sold 6.44 million shares of common stock at $36 per share for over $231 million. ■ Tricida's future was entirely dependent on the success of brining veverimer to market: veverimer was Tricida's only drug candidate, so the day-to-day operations throughout the class period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization.

Statements About the Enrollment of the Postmarketing Confirmatory VALOR-CKD Trial				
D1	Klaerner, 3/29/2019, 2018 10-K	"We had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial and initiated the trial in late 2018 in the United States and other countries with an anticipated sample size of approximately 1,600 subjects. * * * We anticipate that the VALOR-CKD trial will randomize approximately 1,600 subjects in order to show a 30% to 35% reduction in renal events, defined for purposes of the VALOR-CKD trial as a ≥ 40% reduction in eGFR, ESRD or renal death. * * * Based on the magnitude of the increase in blood bicarbonate observed in our pivotal Phase 3 trial, TRCA-301, and the inverse relationship between blood bicarbonate and risk of renal events described by the Predictive MA Model, we have determined that randomizing 1,600 subjects to TRC101 or placebo in a 1:1 ratio will result in 90% power to show a 30% to 35% reduction in renal events in the VALOR-CKD trial."	Regardless of what Tricida had previously anticipated the necessary VALOR-CKD patient enrollment to be, by March 2019 Tricida had set a target internally of enrolling 4,000 patients in the VALOR-CKD trial, according to CW1. The ADL disclosed by Tricida on February 25, 2021 confirmed the inadequacy of a 1,600-subject VALOR-CKD trial. One of the veverimer NDA's deficiencies identified by the FDA was the underpowered state of the VALOR-CKD trial: "The OND also concluded that the confirmatory trial, VALOR-CKD, is underpowered to detect the effect size (13%) predicted by the original Tangri model (also known as the Predictive MA Model) based upon the placebo-subtracted mean treatment effect observed in the TRCA-301/TRCA-301E trial." The false statements about the VALOR-CKD trial's sample size were material because they misrepresented the VALOR-CKD trial to be adequately powered to confirm the TRCA-301/TRCA-301E's findings with clinical evidence of efficacy. This, in turn, concealed the actual risk that	■ Klaerner was intimately acquainted with the enrollment details of the VALOR-CKD trial. ■ According to CW1, Klaerner was infuriated by the slow pace at which subjects were being enrolled in the VALOR-CKD trial, and, at meetings attended by CW1 in June 2019, "screamed" at PRA employees for failing to recruit enough patients. ■ Tricida was Klaerner's personal project, and he was involved in and aware of more than just the core operations at Tricida. He "started it in 2013 in his living room" shortly after "finishing up the Relypsa experience" and he "was looking for an opportunity to create something that is truly disease-modifying." Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is "very passionate about polymer chemistry," and demonstrates himself to be intimately familiar with the design and functionality of veverimer. ■ Klaerner was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. According to CW1, Klaerner attended numerous meetings about patient recruitment and enrollment for the
D2	Klaerner,	Same		

	4/3/2019, Secondary Offering Rule 424(b)(4) Prospectus		the FDA would reject the veverimer NDA.	VALOR-CKD trial. Klaerner also attended meetings with and inspections by the FDA. For example, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019 reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, CW 2 stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency. CW2 also stated that Klaerner was even specific about where he wanted to hold the veverimer launch party, insisting to CW2 that the party be held at the Ritz-Carlton Hotel at Half Moon Bay despite CW2's concern that such an expensive location might not please the FDA. ■ Klaerner is an experienced clinical stage pharmaceutical company executive, having founded two clinical stage companies prior to Tricida—one of which (Ilypsa) was acquired by Amgen, Inc. and the other of which (Relypsa) went public before being acquired by Galencia Ltd. In his own words, he's "done this now 3 times," taking "an idea … to a commercial product." ■ Tricida had committed in prior SEC filings to "obtain[ing] the FDA's agreement and finaliz[ing] the design of our confirmatory postmarketing trial, VALOR-CKD, and completely enroll[ing]
D3	Klaerner, 5/1/2019, 1Q19 10-Q	"We had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial and initiated the trial in late 2018 in the United States and other countries with an anticipated sample size of approximately 1,600 subjects."		
D4	Klaerner, 11/14/19, 3Q19 10-Q	"We anticipate the VALOR-CKD trial will randomize approximately 1,600 subjects and is currently estimated to complete enrollment in mid-2020."		
D5	Klaerner, 3/29/2020, 2019 10-K	"Based on the magnitude of the increase in serum bicarbonate observed in our pivotal Phase 3 trial, TRCA-301, and the inverse relationship between serum bicarbonate and risk of renal events described by the Predictive MA Model, we have determined that randomizing 1,600 subjects to veverimer or placebo in a 1:1 ratio will result in 90% power to show a 30% to 35% reduction in renal events in the VALOR-CKD trial."		
D6	Klaerner, 6/12/2019,	"We -- under that accelerated approval path, we obviously have a post-marketing		

	Speaking at Goldman Sachs Global Healthcare Conference	commitment to show that our surrogate is going to translate to clinical benefit. And the VALOR-CKD study is a time-to-event study with 1,600 patients that is a one-to-one randomized double-blind study. We're conducting it in all over the world, in 33 countries and up to 350 sites. And it's underway. And we hope to -- and we are on track to really have this sufficiently recruited to submit our NDA in the second half of this year. * * * Ultimately, the study is powered to show a 30% reduction in renal progression, as measured in a slightly different endpoint, DD40. So it's renal death, dialysis and 40% eGFR reduction. And again, with 1,600 subjects, 800 on active, 800 on placebo, we control a 30% reduction in the time to that event."		or nearly completely enroll[ing] our confirmatory postmarketing trial, VALOR-CKD- prior to the submission of an NDA," so the most reasonable inference to draw is that Klaerner falsely represented the VALOR-CKD sample size to be lower than it needed to be. ■ Klaerner had a motive to lie: Tricida was struggling to recruit enough patients for the confirmatory trial, but the Company had repeatedly told investors that the NDA would be filed in the second half of 2019. Tricida would not be able to appear to have nearly fully enrolled the VALOR-CKD trial in time with an unobtainable target enrollment. ■ During the class period, Klaerner made 34 sales of Tricida stock, totaling $9,758,875. ■ Tricida needed funds to operate and carry out its postmarketing trial commitment, so it sold common stock to the investing public in the IPO. ■ Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018 and needed additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA date, so Tricida sold 6.44 million shares of common stock at $36 per share for over $231 million. ■ Tricida's future was entirely dependent on the success of brining veverimer to market: veverimer was Tricida's only

				drug candidate, so the day-to-day operations throughout the class period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization.
Other Statements about the Veverimer NDA and Supporting Trials				
E1	Klaerner, 6/12/2019, Speaking at Goldman Sachs Global Healthcare Conference	"And when you fast-forward in all the work that we've done, from a discovery to an early development, to a late stage development, agreeing with FDA, an accelerated approval path, you -- all you expect to do is to show a surrogate effect, and then you have a post-marketing commitment that ultimately then, you confirm that, that surrogate is going to translate. Now we found ourselves with 1-year safety extension data that showed clinical benefit."	There is nothing easier about shepherding drug candidates through the accelerated approval process. Drug candidates evaluated via the ADA must still meet the same statutory standards for safety and efficacy: substantial evidence based on adequate and well-controlled clinically investigations. *See* Moscicki, *FDA's Breakthrough Therapy Designation*, *supra*; 21 U.S.C. § 355(d); 21 C.F.R. § 314.126. And Drugs granted accelerated approval must promptly conduct post-marketing confirmatory trials to verify clinical benefit, all of which dictates a more rapid pace of development. Moscicki, *FDA's Expedited Review Programs*, *supra*. The related time crunch was evident in Tricida's inability to adequately recruit their VALOR-CKD trial prior to the pre-planned NDA submission window. Moreover, where the surrogate endpoint itself has yet to be accepted by the FDA as	■ Regulations and well-established FDA guidance require foreign data to be applicable to the U.S. patient population and U.S. medical practice. ■ It is well established that "geographic, socio-economic, infrastructure, cultural and educational features" of "the Eastern European nephrology community" mean that "[s]everal aspects of CKD differ significantly" compared with Western Europe, which is generally considered to be the most U.S.-like foreign region besides Canada. ■ Well-established FDA guidance instructs that when a sponsor relies upon a single Phase 3 study, the FDA expects that single trial to be a large multicenter study in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen. ■ Klaerner knew the patient enrollment details for the TRCA-301/TRCA-301E trial. ■ Tricida was Klaerner's personal project, and he was involved in and aware of more than just the core operations at Tricida. He "started it in 2013 in his living room"

			reasonably likely to demonstrate clinical efficacy, the drug sponsor faces the additional obstacle of convincing the FDA that the chosen surrogate endpoint is clinically relevant. If anything is to be said about the ADA, it is that the ADA presents more obstacles towards approval than the traditional path, not fewer. Further complicating matters, Tricida was proceeding through the ADA with only a single Phase 3 efficacy trial, which meant that it would—and did—receive enhanced scrutiny from the FDA. This information was material to any investor's assessment of the risk that veverimer would or would not receive FDA approval, and its omission from the statement suggesting that approval along the ADA is easier than the traditional approval path further enhanced the false and misleading nature of the statement.	shortly after "finishing up the Relypsa experience" and he "was looking for an opportunity to create something that is truly disease-modifying." Klaerner, who has a Ph.D. in polymer and organic chemistry and was an in-house scientist before founding several companies, is "very passionate about polymer chemistry," and demonstrates himself to be intimately familiar with the design and functionality of veverimer. ■ Klaerner was focused on the details and, given the small size and narrow focus of the Company, participated in meetings with lower-level employees working toward accomplishing a single component of the data needed to support an NDA. According to CW1, Klaerner attended numerous meetings about patient recruitment and enrollment for the VALOR-CKD trial. Klaerner also attended meetings with and inspections by the FDA. For example, the Establishment Inspection Report for the inspection of Tricida's South San Francisco facility from December 9-17, 2019 reports that the FDA inspector met with Klaerner before the facility inspection and afterwards to debrief the results. Additionally, CW 2 stated that at numerous meetings, Klaerner told the assembled company executives that he was waiting to hear from the FDA about setting up a meeting with the Agency. CW2 also stated that Klaerner was even specific about where he wanted to hold

				the veverimer launch party, insisting to CW2 that the party be held at the Ritz-Carlton Hotel at Half Moon Bay despite CW2's concern that such an expensive location might not please the FDA. ■ Klaerner is an experienced clinical stage pharmaceutical company executive, having founded two clinical stage companies prior to Tricida—one of which (Ilypsa) was acquired by Amgen, Inc. and the other of which (Relypsa) went public before being acquired by Galencia Ltd. In his own words, he's "done this now 3 times," taking "an idea … to a commercial product." ■ Risk disclosures in the IPO Prospectus, secondary offering prospectus, and all 10-Qs and 10-Ks during the class period acknowledged, "The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice." ■ Risk disclosures in the IPO Prospectus, secondary offering prospectus, and all 10-Qs and 10-Ks during the class period warned, "We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data …." ■ These risk disclosures demonstrate that Tricida was aware of the risk posed by using clinical data from a patient population outside the United States that

				is materially different from the United States patient population, and they demonstrate that Tricida was aware of the risk posed by majority enrollment in Eastern European sites. ■ During the May 2020 late-cycle review, the FDA raised long-standing concerns about the comparability of the TRCA-301/TRCA-301E trial subjects to the U.S. patient population and U.S. medical practice. ■ During the class period, Klaerner made 34 sales of Tricida stock, totaling $9,758,875. ■ Tricida needed funds to operate and carry out its postmarketing trial commitment, so it sold common stock to the investing public in the IPO. ■ Tricida had $243.4 million in cash, cash equivalents, and investments at the end of 2018 and needed additional monies to fund its operations past early 2021, when the Company would be in the initial stages of commercializing veverimer if the NDA were approved by the PDUFA date, so Tricida sold 6.44 million shares of common stock at $36 per share for over $231 million. ■ Tricida's future was entirely dependent on the success of brining veverimer to market: veverimer was Tricida's only drug candidate, so the day-to-day operations throughout the class period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization.

				statement.
E2	Klaerner, 6/12/2019, Speaking at Goldman Sachs Global Healthcare Conference	"We have the ability to submit our NDA with just one pivotal trial that shows a surrogate effect, and we've completed that.."	Klaerner misleadingly presented the single phase 3 efficacy trial as a strength—something increasing the likelihood that the FDA would approve veverimer— when in fact it was a significant risk to FDA approval of the NDA. Tricida knew that the TRCA-301/TRCA-301E trial would receive enhanced scrutiny from the FDA. Klaerner's statement presenting the submission of an NDA based on a single pivotal trial to be an accomplishment was, accordingly, false and misleading. It was materially so because it inflated the investing public's perception of the likelihood that veverimer would receive FDA approval.	Same as above.
E3	Klaerner, 5/7/2020, Speaking 1Q20 Earnings Call	"In our Day 74 letter, the FDA indicated that they plan to hold an advisory committee meeting or AdCom to discuss the application. In our late-cycle meeting with the FDA held in May 2020, the FDA indicated it currently does not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19. In our late-cycle meeting with FDA, we took the opportunity to address outstanding review issues. We presented our data	The reason why the FDA indicated it currently does not plan to hold an AdCom to discuss veverimer" was not, primarily, due to the logistical challenges posed by COVID-19, but instead due to the FDA's concerns that there were too many problems with the NDA to even warrant convening an Advisory Committee. Plus, by discussing the data underling the clinical trial and the "outstanding clinical review issues" Klaener misled investors by omitting to reveal the	■ During Tricida's late cycle meeting with the FDA, held in May 2020 prior to the May 7, 2020 earnings call, Tricida addressed two substantive review issues that the FDA had raised in advance of the meeting: concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population. Klaerner undoubtedly attended the late-cycle meeting and knew

		and rationale as to why we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials."	FDA's concerns regarding the trial data supporting TRCA-301, that the majority of participants were from Eastern Europe and the high concentration in one trial site. Tricida confirmed as much in its 2Q20 10-Q, filed August 6, 2020, in which the Company disclosed,"In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population." Given the magnitude of these issues, the Company said in the 2Q20 10-Q that it was likely to receive a CRL. These review issues proved to be the main reasons for the FDA's rejection of veverimer, as the Company finally spelled out in a February 25, 2021 press release titled "Tricida Has Received an Appeal Denied Letter from the Office of New Drugs of the FDA in	before the meeting of the substantive review issues raised by the FDA.

			Response to its Formal Dispute Resolution Request."	